No. 86 1887

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

WILLIAM J. MAYERS, D.C., and
PATRICIA M. MAYERS,

Petitioners,

– against –

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether the Civil Monetary Penalties & Assessment Act, 42 U.S.C. §§ 1320a-7a *et seq.* (1983 & Supp. 1987), is unconstitutional on its face and as applied;

2. Whether the Civil Monetary Penalties & Assessment Act is, in purpose and/or in effect, a penal statute, or a quasi-criminal statute which requires commensurate constitutional protections;

3. Whether the Civil Monetary Penalties & Assessment Act requires proof of knowledge, intent to defraud, or knowingly fraudulent conduct;

4. Whether the Civil Monetary Penalties & Assessment Act, and/or its implementing regulations, relied upon below, are unlawfully vague or ambiguous;

5. Whether unpublished, informal rules and directives of the Secretary of Health and Human Services and/or of Blue Cross Blue Shield of Florida are substantive and denied to petitioners due process notice in violation of the Administrative Procedures Act, 5 U.S.C. §§ 553 *et seq.* (1977).

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

OPINIONS BELOW

The opinion of the Court of Appeals (App. A)[1] was filed on December 22, 1986, and is reported at 806 F.2d 995 (11th Cir. 1986). The order of the Court of Appeals denying petitioners' Petition for Rehearing and Rehearing En Banc was filed on February 26, 1987, and is not reported. (App. B). The final decision of the Secretary of Health and Human Services (App. C) was filed on August 11, 1985, and is not reported.

[1] References to the Appendix annexed hereto are designated "App. ."

JURISDICTION

Petitioners appealed to the Court of Appeals pursuant to 42 U.S.C. § 1320a-7a(d)(1983). The decision of the Court of Appeals was entered on December 22, 1986. Petitioners' timely filed petition for Rehearing and Rehearing En Banc was denied, and was entered on February 26, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

The pertinent sections of the Civil Monetary Penalties and Assessment Act, 42 U.S.C. §§ 1320a-7a *et seq.* (1983 & Supp. 1987), and the Fifth and Fourteenth Amendments (U.S. Const. amends. V, XIV) are reproduced in the Appendix annexed hereto. App. E-I.

PARTIES TO THE PROCEEDING

The petitioners are William J. Mayers, D.C., and Patricia M. Mayers.

The respondent is the United States Department of Health and Human Services.

STATEMENT

Petitioners William J. Mayers, D.C., and Patricia M. Mayers, petition this Court for relief following affirmance by the Court of Appeals, based upon the Court's application of the incorrect standard of knowledge required under the Civil Monetary Penalties & Assessment Act, 42 U.S.C. § 1320a-7a, *et seq.* (1983 & Supp. 1987)("CMPAA"). The United States Department of Health & Human Services ("HHS") administers and regulates the federal Medicare and Medicaid programs. At issue here is the imposition of penalties and assessments against Dr. and Mrs. Mayers in the amount of $1,791,100.00 (plus a 25 year suspension from participation in the Medicare Program) for allegedly false claims upon which they received $24,697.73.

The Court of Appeals based its decision on a misapplication of the statutory requirement for knowledge. On April 27, 1987 – three weeks ago – the Secretary of HHS, through his designee, the Under Secretary of HHS (the "Secretary"), admitted that the Court of Appeals in this case applied the incorrect legal standard. *In the Matter of the Inspector General* v. *Frank P. Silver, M.D.*, HHS Grant Appeals Board, Docket No. C-19 (April 27, 1987)(App. D). *See* discussion, *infra*.

Dr. Mayers became a licensed chiropractor in the early 1960's. He moved with his wife and three children in 1975 to Florida. In 1976 he opened a practice in Cape Coral, the Del Prado Chiropractic Center, where he practiced chiropractic medicine for eight years.[2] Mrs. Mayers had worked with her husband since he opened the Del Prado Center in 1976; her function had always been as a bookkeeper, processing claims, including billings for reimbursable chiropractic Medicare claims. In June, 1982, Dr. Mayers became associated with medical doctors, an osteopathic physician, and a naturopath and expert in neurovascular testing (plethysmography). In 1982, in conjunction with the hiring of the Center's first full-time medical doctor, Dr. Mayers began to take assignments of Medicare claims; at this time the Lee County Medical and Professional Center was formed.[3]

The patient population at the Center is predominantly senior citizens. Muscular skeletal problems are dominant in this patient population; medical treatments and therapies rendered at the Center, which are indicated for such population-specific ailments, include, among other things, diathermy, extensilizer, and intersegmental traction, commonly referred to as stabilizer treatment. These services are reimbursable by Medicare as medical

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[2] The Del Prado Chiropractic Center began operating in Cape Coral in 1976; Lee County Medical and Professional Center began operating at the same location in approximately October, 1982; Lee County Medical and Chiropractic Center began operating in North Fort Myers in January, 1984. In the Spring of 1984, the Cape Coral offices were closed.

[3] Medicare reimburses certain payments rendered by a "physician;" the physicians relevant to this case are medical doctors and doctors of chiropractic.

services. The particular course of intensive treatment adopted at the Center, which combined those therapies and treatments above-mentioned, along with chiropractic manual manipulations of subluxations of the spine, or "adjustments," are beneficial healthcare procedures and techniques. Under the applicable laws and regulations of the State of Florida, licensed chiropractors can render and supervise these physical therapies and treatments, operate the relevant equipment, and take and read x-rays.

On or about February 28, 1984, Dr. and Mrs. Mayers received a letter notifying them that Blue Cross Blue Shield of Florida, Inc. ("BCBSF"), on orders from HHS, was suspending their in-process and future Medicare reimbursements pending an investigation of alleged fraud. Instead of granting Dr. Mayers the suspension hearing to which he was entitled, HHS commenced a CMPAA proceeding.[4]

The CMPAA provides that a provider may be penalized a maximum amount of $2,000.00 for each "item" for which Medicare is billed which the provider knows or has reason to know was

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[4] On March 19, 1984, Dr. Mayers commenced an action in the United States District Court for the Middle District of Florida, seeking a preliminary and permanent injunction preventing BCBSF, on the orders of HHS or otherwise, from suspending such reimbursements prior to a hearing. 42 U.S.C. § 1395y(d)(3) permits HHS, as opposed to its delegated carrier, to suspend reimbursement payments pending investigation of alleged fraudulent Medicare billing practices; 1395y(d)(3), however, unlike 1395(u), provides a specific mechanism for an administrative hearing, and appeal, and for judicial review of an adverse determination by HHS against the provider, pursuant to 42 U.S.C. § 405(g) (1983). Future payments may be suspended only under § 1395y(d)(3). *Klein v. Heckler*, 761 F.2d 1304, 1310 (9th Cir. 1985). The matter was heard by the Honorable Elizabeth A. Kovachevich, U.S.D.J., who entered an Order on April 30, 1984, directing HHS to provide an administrative forum for determining the present and future suspended reimbursement payments to Dr. Mayers. Rather than doing so, however, by letter dated May 3, 1984, the Deputy Inspector for Civil Fraud notified Dr. and Mrs. Mayers that HHS was proposing to impose CMPAA sanctions against Dr. Mayers and his wife. Having done so, HHS then misled Judge Kovachevich into believing that an appropriate forum had been provided, and she entered an Order on May 25, 1984, dismissing Dr. Mayers' action. To date, HHS has failed to provide a payment suspension hearing to Dr. Mayers.

not provided as claimed, or which is simply not reimbursable by Medicare. The statute also provides for imposition of a penalty of twice the total amount billed, rather than the amount received. In this case, Dr. Mayers and his bookkeeper, Mrs. Mayers, had submitted claims for Medicare reimbursement, which they believed were appropriate, amounting to $145,550.00, and for which they were reimbursed, pursuant to BCBSF's formula, less than $25,000.00. These bills contained 2,702 individual "items;" thus, the maximum penalty which could have been imposed was $5,404,000.00 (2,702 X $2,000), plus $291,100.00 ($145,550 X 2), for a total of $5,695,100.00. Apparently troubled about the obvious disparity between the authorized maximum penalty and the "loss" to the Government, HHS sought to impose a penalty of "only" $2,900,000.00 against petitioners.

Each of the 2,702 items was a claim for services rendered and actually provided during a time when a medical doctor who ordered the service was not physically present at the Center.[5] No contention was made in the CMPAA charges that services were not rendered or that the services were not rendered and/or supervised by a licensed physician, to wit, a chiropractic physician, pursuant to instructions and orders of a medical doctor.[6] The problem, HHS averred, was that during the short intervals when the challenged services were furnished, no licensed medical doctor performed the service or was present and "personally" supervising the performance of the service by one of his employees. The issue thus posed by HHS in the CMPAA proceeding was whether the Mayers knew or should have known that submission by the Center of claims for Medicare reimbursement for services actually rendered by licensed chiropractic physicians, or under the immediate personal supervision of licensed

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[5] HHS cut off all communications and dialogue with petitioners and prevented them from obtaining responses to unresolved billing and record-keeping questions upon the directive of an HHS investigator to BCBSF that its auditor was not to contact petitioners again or assist them with their unanswered questions relating to, for example, reimbursable services and supervision rendered by a chiropractor "incident" to a "physician's" services.

[6] 42 U.S.C. § 1395x(r)(5) (1983 & Supp. 1978) defines "physician" and includes a duly licensed chiropractor.

chiropractic physicians, which were properly reimbursable if a medical doctor was on the premises, were fraudulent. Answering that question in the affirmative, the Secretary, after an administrative "hearing," imposed a "lenient" penalty of $1,791,100.00, and suspended petitioners from participation in the Medicare program for twenty-five years.

The Secretary's final decision concluded that petitioners knew or should have known that their submissions of bills seeking reimbursement for services actually and uncontestably rendered pursuant to a medical doctor's orders, during an interval of time when such medical doctor was not on the premises, but performed by or under the direct, personal supervision of a chiropractic physician, were fraudulent claims for services not provided as claimed. (Final Decision of the Under Secretary, 8/11/85, App. C.) For this, the penalties and assessments -- for "wrongful" receipt of less than $25,000.00 -- was $1,791,100.00. *Id*[7].

In affirming the Secretary's final order, the Court of Appeals ruled that the CMPAA, because of its "civil" label, is not unconstitutional on its face or as applied, is not an unconstitutional penal statute, and does not, therefore, require proof of guilty knowledge or intent to defraud.

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[7] The Secretary's imposition of sanctions was arbitrary and capricious, and an abuse of discretion. The Secretary imposed an unconstitutional penal sanction, without the protections inherent in penal proceedings, all in violation of 5 U.S.C. § 706(2), which sets forth the applicable standards of review.

REASONS FOR GRANTING THE WRIT

In *Mayers* v. *United States Department of Health and Human Services*, 806 F.2d 995 (11th Cir. 1986), the Court of Appeals for the Eleventh Circuit "decided an important question of federal law which has not been, but should be settled, by this Court." Sup. Ct. R. 17(1)(c). The Court of Appeals decided that the CMPAA, 42 U.S.C. § 1320a-7a (1983 & Supp. 1987),[8] is constitutional and provides all of the protections mandated by the principles of due process.

In its present posture, this case raises important substantive and procedural issues that relate to the integrity of the administration of the Federal Medicare program and to the constitutional rights of healthcare providers under the program. The Court of Appeals ruling necessarily will discourage providers from participating in the Medicare program and will deprive eligible, deserving Medicare beneficiaries of quality healthcare to the detriment of the national public interest.

I

LIABILITY UNDER THE CMPAA CANNOT BE FOUND UPON NEGLIGENCE, MISTAKE, OR INADVERTENCE; PROOF OF INTENT MUST BE ESTABLISHED

The CMPAA authorizes the Secretary of HHS to impose penalties and assessments upon proof that a person presented or caused to be presented a claim for an item or service which the person "knows or has reason to know" was not provided as claimed, or which claim or service is simply not reimbursable by Medicare. Social Security Act § 1128A, 42 U.S.C. § 1320a-7 (a)(1)(1983). Petitioners submit that the CMPAA, its enabling regulations, and informal rules promulgated by the Secretary, are unconstitutional on their face and as applied to Dr. and Mrs. Mayers.

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[8] The regulations implementing the CMPAA are codified at 45 C.F.R. §§ 103.100-133 (1986).

A. THE STATUTORY AND REGULATORY SCHEME

1. *The Medicare Reimbursement Program*

Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.* (1983 & Supp. 1987), establishes the Medicare program of health insurance for the aged and disabled. The Medicare program consists of two substantive sections, Part A and Part B. Part A provides insurance for hospital and related post-hospital services for eligible beneficiaries through direct payments to hospitals, nursing homes, clinics or home health agencies. 42 U.S.C. §§ 1395c-1395i-2 (1983 & Supp. 1987). Part B provides a voluntary subscription program of supplementary medical insurance in which beneficiaries may enroll. Under Part B, Medicare pays 80% of the "reasonable charges" for certain medical and other healthcare services, such as physicians' services, x-rays, laboratory tests, drugs, and related services. 42 U.S.C. §§ 1395j-1395w (1983 & Supp. 1987). Part C of Title XVIII contains miscellaneous provisions applicable to the programs under both Parts A and B. 42 U.S.C. §§ 1395x-1395xx (1983 & Supp. 1987). This case involves only the Part B program.

2. *The Medicare Program Part B*

The Secretary is responsible for administering the Medicare program. 42 U.S.C. §§ 1395hh, 1395kk (1983). In order to provide maximum efficiency and convenience for eligible beneficiaries and providers of services, Congress authorized the Secretary to contract with carriers, frequently private insurance carriers such BCBSF, to perform designated functions. Part B benefits are paid through carriers, under contract with the Secretary. 42 U.S.C. §§ 1395u, 1395u(f) (1983 & Supp. 1987).

Medicare benefits under Part B provide for payment for "medical and other health services furnished by a provider of services or by others under arrangement with them. . . . " 42 U.S.C. § 1395k(a)(2)(B)(1983). Pursuant to 42 U.S.C. § 1395x(s) (1983 & Supp. 1987), the term "medical and other health services" includes physician services, as well as services and supplies furnished "incident to" a physician's professional services.

B. THE CMPAA REQUIRES PROOF OF KNOWLEDGE

The CMPAA authorizes the Secretary to impose upon a Medicare or Medicaid provider massive penalties and assessments, plus suspension from the program. The statute provides for the imposition of a penalty of up to $2,000.00 for each item or service falsely claimed, or which is not reimbursable, together with an assessment of up to twice the amount claimed for each such item or service in lieu of damages sustained by the government or the state agency because of such claim. 42 U.S.C. § 1320a-7a(a)(1983 & Supp. 1987).

In addition, the CMPAA authorizes the Secretary to suspend providers who are found liable under the statute from participation in the Medicare and Medicaid programs for an indefinite period. 42 U.S.C. § 1320a-7(c) (Supp. 1987).[9] *See generally* Kusserow, *Civil Money Penalties Law of 1981: A New Effort To Confront Fraud and Abuse in Federal Healthcare Programs*, 58 Notre Dame L. Rev. 985 (1983).

In *Mayers*, the Eleventh Circuit held that liability under the CMPAA, and, thus, massive and severe money penalties and suspension from participation in federal and state health insurance programs, can be imposed and sustained without demonstration of knowledge or intent, and without any burden more stringent than a preponderance of the evidence. *Mayers*, 806 F.2d at 999-1000. It affirmed a penalty and assessment of $1,791,100.00 on the grounds that the petitioners submitted claims which they "knew or had reason to know" were not provided as claimed. *Id.* Specifically, the court found that Dr. Mayers, a chiropractor, could not receive reimbursement for any services, other than manual manipulations of the spine, rendered

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[9] Pursuant to the statutory and regulatory scheme, an appeal of the suspension portion of the CMPAA is perfected by initiating a suit in the District Court. 42 U.S.C. § 1320a-7(e) (Supp. 1987). Petitioners' appeal of their suspension from the Medicare Program, styled *Mayers* v. *Bowen*, Case No. 86-84-CIV-FtM-17B, is presently pending before the Honorable Elizabeth A. Kovachevich, United States District Judge, Middle District of Florida. The matter had been stayed pending final disposition of this case.

or supervised by him, and that claims for reimbursement for services outside this narrow category violated the Medicare statute.[10] In reaching its decision, the Court rejected petitioners' argument that they believed that their claims were properly reimbursable as services rendered as an "incident to" a medical physician's ongoing care within the meaning of the Medicare Act.[11] Notwithstanding petitioners' demonstration that "incident to" is nowhere defined in the Medicare statute or regulations, the Court affirmed the Secretary's finding that the *plain language* of the Medicare statute put a physician on notice that the reimbursement of ancillary services rendered as an "incident to" his professional care was wholly and completely conditioned on that same physician ordering and supervising the rendering of those services by ancillary personnel *employed by* him.[12]

In response to petitioners' argument that the legal standard to be applied in order for liability to attach is unascertainable from the statutory phrase "knows or has reason to know," the Eleventh Circuit concluded that the CMPAA was sufficiently

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[10] A doctor of chiropractic is included within the definition of "physician" under the Medicare statute. 42 U.S.C. § 1395x(r) (1983 & Supp. 1987). He is a physician for purposes of section 1861(s)(1) and 1861(s)(2)(A) of the Social Security Act, which sections set forth the medical and health services reimbursable to physicians, including doctors of chiropractic. Section 1861(b)(2)(A), codified at 42 U.S.C. § 1395x(s)(2)(A), specifically renders reimbursable under Medicare "services and supplies . . . furnished *as an incident to a physician's professional service.*" *Id.* (emphasis added). "Physicians' services" are defined in 42 U.S.C. § 1395x(q) (1983). Petitioners reasonably concluded that they could receive reimbursement for services rendered by Dr. Mayers directly, within his capacity as a physician under 42 U.S.C. § 1395x(r)(5), or as an incident to another physician's services, under 42 U.S.C. §§ 1395x(q), 1395x(s)(2)(A).

[11] The Court of Appeals rejected petitioners' allegations that the Medicare Act and its implementing regulations were vague and ambiguous. It found that the statute is clear with respect to the services reimbursable to petitioners, with respect to the meaning of "incident to," and with respect to the requisite standard of knowledge. *Id.* at 1000.

[12] The Court failed to consider petitioners' argument that the Medicare statute can reasonably be read to provide for reimbursement to chiropractors for items and services rendered as an "incident to" another physician's care.

specific to give petitioners notice and, thus, not in violation of petitioners' due process rights. The Eleventh Circuit's decision has since been directly contradicted and rejected by the Secretary.

In *Inspector General* v. *Frank P. Silver, M.D.*, HHS Departmental Grant Appeals Board, Docket No. C-19 (April 27, 1987)(*see* App. D), the Secretary stated:

> In *Mayers* v. *U.S. Dept. of Health and Human Services*, No. 85-3803 (11th Cir. Dec. 22, 1986), for instance, the court confused the "should know" standard and the "reason to know" standard treating the two as if they were equivalent. *Id.* at 41.

The Secretary sought to lessen the impact of his admission that the Court of Appeals dealt an unconstitutional blow to Dr. and Mrs. Mayers by averring that the "court's 'error,' such as it was, had no affect on its holding." *Id.* Contrary to the Secretary's misguided backstep and to quote the Secretary himself, quoting Roger Traynor:

> 'To err is human, as a judge well knows, but to err is not always harmless.' Traynor, The Riddle of Harmless Error 3 (1970). *Id.*

In this case, the error definitely was not harmless.[13]

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[13] Upon the Secretary's remand of *Silver* to the Administrative Law Judge ("ALJ"), the ALJ entered an order (Order, Docket No. C-19, April 30, 1987, Hon. Charles E. Stratton, ALJ) directing further proceedings consistent with the Secretary's remand and analysis of the "knows or has reason to know" standard:

> 1. The [CMPAA] requires the Inspector General to establish affirmatively that the Respondent actually knew or had reason to know that improper claims were being submitted on his behalf. Page. 20.
>
> 2. The term "knows" in the phrase "knows or has reason to know" refers to *actual* knowledge and not to knowledge the actor should have had, had he acted reasonably. Page 28. (Emphasis added).
>
> • • •

(Footnote Continued)

The CMPAA is intended to be the Secretary's weapon to detect, and punish fraud in the Medicare and Medicaid programs. The legislative history confirms that the CMPAA's central and primary concern is fraud and fraudulent conduct. *See* H.R. Rep. No. 158, 97th Cong., 1st Sess. 327-29 (1981); House Subcomm. on Health of the Comm. on Ways and Means, 96th Cong., 1st Sess., Report on Medicare Amendments of 1979 – H.R. 3990 and H.R. 4000: Summary, Justification, Explanation, and Comparison with Present Law 61 (Comm. Print 1979); *Programs of the Public Health Service Act – Oversight: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. 22 (1979) (statement of Leonard Schaeffer, Administrator of HHS' Healthcare Financing Administration). The Eleventh Circuit recognized this fact. *Mayers*, 806 F.2d at 997. What is left unclear from the CMPAA's statutory and regulatory scheme, and from its legislative history, and what is at issue in this case, is the standard of knowledge or intent constitutionally necessary to sustain liability for fraud under the statute.

The CMPAA expressly states that liability is dependent upon a finding that the provider "knows or has reason to know" that the services for which reimbursement is sought were not rendered as claimed. 42 U.S.C. § 1320a-7a(a)(1)(A). The statutory phrase "knows or has reason to know" is qualitatively different[14] from

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4. The Inspector General now concedes, and the Deputy Under Secretary finds, that it is not sufficient to prove that the Respondent should have known that the claims were improper. Pages 10-11. "Should have known" implies a duty to ascertain all pertinent information. Page 26.

5. "Reason to know" means that a duty to investigate arises only after an actor learns of pertinent information. "Reason to know" severely restricts the meaning of the word "knows." Page 26.

6. The term "knows" in the CMPL does not mean extreme carelessness, negligent misrepresentation, or reckless disregard. Page 26.

[14] "Reason to know" and "should have known" give rise to different legal obligations and duties. *See, e.g., Blackwell* v. *Sun Elec. Corp.*, 696 F.2d 1176, 1183

(Footnote Continued)

"knows or should have known."[15] Neither the CMPAA nor its regulations explain the degree or quality of knowledge sufficient to meet the standard of "knows or has reason to know" for purposes of proving the elements of liability under the CMPAA.[16] In order to prevail on a cause of action pursuant to the CMPAA, the Government clearly must prove that petitioners had the requisite level of knowledge. Petitioners' inability to ascertain that legal standard, however, because the CMPAA is ambiguous and does not address the meaning of "knows or has reason to know," renders them unable both to determine whether their conduct violates the statute, or to defend against conclusory allegations that they had sufficient knowledge to satisfy the "knows or has reason to know" requirement.

The Eleventh Circuit summarily disposed of petitioners' argument, allegedly in reliance on the clear language of the statute, and held that "knows or has reason to know" does not mean actual knowledge, but something less. *Id.* at 999-1000. The Court

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(6th Cir. 1983); *Stern* v. *American Bank Shares Corp.*, 429 F.Supp. 818, 826-27 (E.D. Wis. 1977); *Green* v. *Equitable Powder Mfg., Co.*, 95 F.Supp. 127, 133 (1951); *United States* v. *Sweet Briar*, 92 F.Supp. 777, 779 (W.D.S.C. 1950); *Buschlen* v. *Ford Motor Co.*, 121 Mich.App. 113, 328 N.W.2d 592, 539 (1982).

[15] "Knows or has *reason* to know" imposes no duty on an individual to inquire as to the existence of a certain fact, but that duty does arise in the context of "knew or should have known." Restatement (Second) of Torts § 12 (Supp. 1986). *See also* Restatement (Second) of Agency § 9 (Supp. 1986). "Knows or has reason to know" has been statutorily defined as requiring *nothing less* than reckless disregard. *See* 31 U.S.C. § 3801(a)(5)(c) (Supp. 1987). Reckless conduct requires a measure of scienter:

> [I]f reckless means something more culpable than negligence, as it must, then an allegation that a defendant merely 'ought to have known' is not sufficient to allege recklessness. *Troyer* v. *Karcagi*, 476 F. Supp. 1142, 1152 (S.D.N.Y. 1979).

[16] In another CMPAA case, in which the petitioner argued that intent had to be proved to sustain an imposition of money penalties, the ALJ acknowledged that both the CMPAA and its regulations neglected to establish liability. *See* 1 CMPR Newslt. at 6 (No. 2, Winter 1987) (discussing *In re Inspector General* v. *Scott*, Docket No. C-15 (1986).

concluded that liability was properly found here because petitioners "knew or *should* have known" that their conduct was wrongful. *Id.* at 1000.[17]

The Eleventh Circuit not only erroneously decided that petitioners possessed the requisite level of knowledge for liability, but it set forth an erroneous legal standard for application by future Courts, and fashioned a formula for liability which is neither supported by the law nor consistent with the type of conduct with which the CMPAA is concerned, *to wit*, fraud.[18] Notwithstanding the statutory language, guilty, actual, or constructive knowledge is commonly construed to be an essential element of a successful cause of action pursuant to civil fraud statutes. For example, the False Claims Act, 31 U.S.C. § 3729 (1983), upon which the CMPAA is modelled, seeks to combat fraud in Government contracts. At all times relevant to this action, the controlling law of the Eleventh Circuit provided that liability under the False Claims Act, 31 U.S.C. §§ 3729-33, requires proof of guilty knowledge.

The recently enacted Program Fraud Civil Remedies Act of 1986, codified at 31 U.S.C. §§ 3801-12 (Supp. 1987), is instructive in determining the meaning of "knows or has reason to know." It provides for the imposition of civil penalties against any person who "knows or has reason to know" that a claim or statement is false or fraudulent. The civil penalty is computed on a basis of $5000 per claim plus an assessment of up to twice

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[17] In the Eleventh Circuit, common-law fraud requires proof that the defendant had knowledge of the falsity of the representation and that such false representation was made with intent. *Pettinelli* v. *Danzig*, 722 F.2d 706, 709 (11th Cir. 1984). Liability for fraud pursuant to the False Claims Act, 31 U.S.C. § 3729 (1983), requires proof of guilty knowledge. *United States* v. *Aerodex*, 469 F.2d 1003, 1007 (5th Cir. 1972); *United States* v. *Priola*, 272 F.2d 589, 594 (5th Cir. 1959).

[18] One of the principal incentives underlying the enactment of the CMPAA was the high incidence of fraud and the low degree of prosecution by the United States Attorneys' Offices. *See* House Subcomm. on Health of the Comm. on Ways and Means, 96th Cong., 1st Sess., Report on Medicare Amendments of 1979 — H.R. 3990 and H.R. 4000; Summary, Justification, Explanation, and Comparison with Present Law 61 (Comm. Print 1979).

the amount *claimed*. Unlike the CMPAA, section 3801 of the statute expressly defines "knows or has reason to know," in part, as follows:

> (5) "knows or has reason to know" for purposes of establishing liability under section 3802, means that a person, with respect to a claim or statement –
>
> (A) has *actual knowledge* that the claim or statement is false, fictitious, or fraudulent;
>
> (B) acts in *deliberate ignorance* of the truth or falsity of the claim or statement; or
>
> (C) acts in *reckless disregard* of the truth or falsity of the claim or statement, and no proof of specific intent to defraud is required.

31 U.S.C. § 3801(a)(5)(A-C)(Supp. 1987)(emphasis added). Although the statute does not require specific intent to defraud, the legislative history clearly explains that mistake, negligence, and even thoughtlessness do not reach the level of knowledge necessary to impose sanctions under the Act.

> In establishing liability under this administrative remedy, the government would not only have to prove that a claim or statement is false, but also that the person "knows or has reason to know" that the claim or statement is false. . . .
>
> The "knows or has reason to know" standard for establishing liability under this section is intended to capture those persons who recklessly disregard facts which are known or readily discoverable upon reasonable inquiry, while excluding those persons who submit false claims or make false statements through mistake, momentary, thoughtlessness, or inadvertence. The definition clarifies, therefore, that a person who makes a false claim or statement through mere negligence does not meet the requisite scienter requirement and would not be held liable under the Act. Only

> those individuals who are extremely reckless, who demonstrate an extreme departure from ordinary care, would be subject to liability.

H. Con. Rep. No. 1012, 99th Cong., 2d Sess. 258-59, *reprinted in* 1986 U.S. Code Cong. & Admin. News 3607, 3904-05. The legislative history of the Program Fraud Civil Remedies Act of 1986, and the statute's articulated definition, clearly demonstrate that the "know or has reason to know" legal standard requires more than negligence and mistake. Although a *specific* intent to defraud is not required by the statute, scienter is imperative before liability can attach.

The Medicare Act is of extreme importance to the entire nation and uniformity in its adminstration is imperative in order that the policies, intentions and spirit of the program are realized. Clearly, the fact that Congress enacted a civil money penalty statute specific to the Medicare Act demonstrates the overwhelming importance of the CMPAA to the Medicare program. As an integral part of the Medicare statute, the CMPAA similarly requires uniformity in its application. Otherwise, its effectiveness as a weapon to combat fraud and sustain the public's confidence in the Medicare program is simply academic. However, the statute's ambiguities obstruct and impede a uniform application of the CMPAA. Unless this Court grants a writ of certiorari to review the Eleventh Circuit's determination, the desired uniformity in application and the essential credibility of the CMPAA itself will be irreversibly sacrificed.

II

THE CMPAA IS UNCONSTITUTIONAL AND UNENFORCEABLE ON ITS FACE AND AS APPLIED TO PETITIONERS

A. THE CMPAA IS A PENAL STATUTE AND IS UNCONSTITUTIONAL

The extent and scope of the civil penalties that can be assessed under the CMPAA for mere negligent or unintentional acts,

or through strict liability if the claim or service is simply not reimbursable by Medicare, cannot by law be construed as a civil penalty.

1. *The Legislative History Demonstrates The Penal Nature Of The CMPAA*

Petitioners were "convicted" on an inadequate showing that they knew or should have known that services rendered were not provided as claimed, or were not reimbursable by Medicare. In consequence, they were subject to, and assessed with, penalties that can only be regarded as being unconstitutionally punitive. Petitioners contend before this Court that the CMPAA is thus an unconstitutional penal statute.

Whether a statute is criminal or civil must be gleaned from its legislative history and the congressional intent, and by reference to statutes upon which it is modelled. *United States* v. *Ward*, 448 U.S. 242, 248, *reh'g denied*, 448 U.S. 916 (1980); *Kennedy* v. *Mendoza-Martinez*, 372 U.S. 144, 168-69 (1963). If Congress did not intend to reach criminal conduct, then the penalties under the CMPAA are so excessive as to violate the Constitution and the CMPAA must be stricken. If Congress did intend to reach criminal conduct, then the procedures, regulations, and standards promulgated or implemented by HHS are inadequate.

2. *The CMPAA Requires Proof Of Fraudulent Conduct*

Congress may not enact a criminal statute, whether or not under the guise of a civil statute, which does not afford to potential violators all of their constitutional protections. The legislative history makes clear that Congress intended to reach criminal conduct. Thus, the CMPAA was intended to reach fraudulent submissions of Medicare claims, and to punish cases of Medicare fraud:

> The [CMPAA] authorizes the Secretary. . . to impose a civil money penalty of not more than $2,000 for each item or service *under a fraudulent claim* for reimbursement under the medicare . . . programs. In addition

> to the penalty, the Secretary would also be authorized to . . . bar from participation in medicare, and the Federal portion of medicaid, *any person determined to have filed a fraudulent claim*. H.R. Rep. No. 158, 97th Cong., 1st Sess. 328 (1981) (emphasis added).

The House Committee Report is particularly illuminating in demonstrating that the CMPAA was intended to be an additional criminal prosecutorial enforcement mechanism:

> Section 16—CIVIL MONEY PENALTY FOR MEDICARE AND MEDICAID FRAUD
>
> Explanation: The intent of the provision is to provide an alternative to criminal proceedings primarily in two types of cases: (1) those in which the behavior of the alleged offender is not likely to warrant imprisonment; and (2) those which are not accepted by United States Attorneys (USAT) for prosecution but which, nonetheless, involve clear violations of Federal statutes or regulations. The latter type of case represents the majority of the *substantiated fraud* cases in the medicare and medicaid programs. These are cases which have been subjected to a full-scale investigation as a result of which there has been a determination that there is *a substantial basis for criminal prosecution*. House Subcomm. on Health of the Comm. on Ways and Means, 96th Cong., 1st Sess., Report on Medicare Amendments of 1979 — H.R. 3990 and H.R. 4000: Summary, Justification, Explanation, and Comparison with Present Law 61 (Comm. Print 1979) (emphasis added).

The Senate Report, Rep. No. 139, 97th Cong., 1st Sess. 565, *reprinted in* 1981 U.S. Code Cong. & Ad. News 396, 832, on the Omnibus Budget Reconciliation Act of 1981, Pub.L.No. 97-35, 95 Stat. 357 (1981), explicitly stated:

> This Section would authorize the Secretary . . . to fine any person who . . . has *filed a fraudulent claim* for Medicare or Medicaid reimbursement. *Id.* at 565 (emphasis added).

Moreover, as set forth in Congressional hearings conducted in 1979, HHS sought authority "to impose civil money penalties *to deter and punish fraudulent providers*." Programs of the Public Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 96th Cong., 1st Sess.22 (1979) (statement of Leonard Schaeffer, Administrator of HHS' Healthcare Financing Administration) (emphasis added).[19]

The legislative history demonstrates that Congress unequivocally intended the CMPAA to provide an alternative mechanism for the "prosecution" of "substantiated fraud cases." House Subcomm. on Health of the Comm. on Ways and Means, 96th Cong., 1st Sess., Report on Medicare Amendments of 1979 — H.R. 3990 and H.R. 4000; Summary, Justification, Explanation, and Comparison with Present Law 61 (Comm. Print 1979). Congress may not disguise that intent merely by labelling the CMPAA as a civil statute. Nor may it punish fraudulent conduct on the basis of a statutory standard that sounds in negligence: "knew or *should have known*" (emphasis added), nor in strict liability if the service turns out not to be reimbursable by Medicare. 42 U.S.C. § 1320a-7a(a)(1)(A), (B) (1983).

3. *The Excessively Punitive Nature Of The CMPAA Demonstrates That It Is A Criminal Statute*

The Supreme Court has stated that whether a particular statutorily defined penalty is civil or criminal is a matter of statutory construction. *United States* v. *Ward*, 448 U.S. 242, 248 *reh'g denied*, 448 U.S. 916 (1980). The inquiry is first whether in establishing the penalty Congress indicated, either expressly or impliedly, a preference for one label or the other, and secondly, where Congress has indicated an intention to create a civil penalty, whether "the scheme was *so punitive* either *in purpose or effect* to negate the intention." *Id.* at 249 (emphasis added).

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[19] Programs of the Public Health Service Act — Oversight: Hearings on the Reauthorization of Some of the Existing Programs and Handling of New Legislation for the Administration and Others Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 96th Cong., 1st Sess. 22 (1979) (statement of Leonard Schaeffer, Administrator of the Health Care Financing Administration) (emphasis added).

The penalties and assessments authorized by and imposed under the CMPAA are unconstitutionally punitive in purpose and in effect.

The CMPAA provides that the Secretary may impose a penalty of up to $2,000.00 for each *line item* or service, plus an assessment of up to twice the amount claimed (as opposed to the amount actually received by the provider) for each item or service. The assessment is intended to be in lieu of damages sustained by the United States.

Under the Regulations, 42 C.F.R. § 405.251(1985), Part B Medicare providers are obligated to itemize the services provided as a condition of reimbursement. It is based upon these specific line itemizations that a penalty under the CMPAA is computed. Thus, errors made in entering or coding the items and/or services can subject providers to substantially disproportionate penalties. Further, if an error is duplicated, the statute penalizes each entry regardless of intent. Thus, a person can be held liable under the CMPAA and subjected to extraordinary monetary fines and suspension from the Medicare program not only for false claims, but for mistakes, negligent or inadvertent acts occurring as a result of the required itemizations, or repetitions of a single innocent error. Such liability may attach where the provider "knows or has reason to know [that the service] was not provided as claimed," 42 U.S.C. § 1320a-7a(a)(1)(A)(1983), or where the claim is simply for a service which in fact is not reimbursable under Medicare. 42 U.S.C. § 1320a-7a(a)(1)(B)(1983). By its very terms, then, the CMPAA is unreasonable, excessive, and unconstitutional. What may have been "intended" as a civil remedy is nothing less than a criminal penalty.

In *Kennedy* v. *Mendoza-Martinez*, 372 U.S. 144 (1963), the Supreme Court set forth the considerations for determining whether a penalty, although labeled civil, is in fact a criminal sanction. These criteria include:

> Whether the sanction involves an affirmative disability or restraint, whether it has historically been regarded as a punishment, whether it comes into play only on

> a finding of scienter, whether its operation will promote the traditional aims of punishment, retribution, and deterrence, whether the behavior to which it applies is already a crime, whether an alternative purpose to which it may rationally be connected is assignable for it, and whether it appears excessive in relation to the alternative purpose assigned. *Id.* at 168-69.

Each of the tests articulated in *Kennedy* v. *Mendola-Martinez*, is met here. Whatever the original intention of the CMPAA may have been, it is a penal statute in purpose and effect, with sanctions that bespeak punishment of a kind not commensurate with a legislative concern for restitution or recoupment; the statute focuses on retribution and deterrence.

In *United States ex rel Marcus* v. *Hess*, 317 U.S. 537, *reh'g denied*, 318 U.S. 709 (1943), in which the Court held that the False Claims Act was a civil remedial statute, the defendant was penalized for knowingly causing the Government to pay claims arising under contracts executed as a result of collusive bidding. The $2,000.00 maximum penalty was computed on 56 separate projects which the Court found were independent instances of fraud. Each of the projects involved fraudulent estimates; the Court did not, however, treat the estimates separately in the penalties calculation, which totalled $112,000.00. *Id.* at 540. An assessment of twice the amount wrongfully received for each claim by the defendant, that is, twice the harm to the Government, was also imposed, totalling $203,000.00. *Id.* Concerning the remedial nature of the assessment, the Court stated:

> As to the double damage provision, it cannot be said that there is any recovery in excess of actual loss for the government, since . . . the double damages is the amount of actual damages proved. *Id.* at 550.

In contrast, the penalties imposed against Dr. and Mrs. Mayers were for claims which totalled $145,550.00, and which resulted in a loss to the Government of less than $25,000.00. The penalty and assessment under the CMPAA was "only" $1,791,100.00; the potential total maximum under the statutory formula was

$5,695,000.00, for a loss to the Government established in a *civil* proceeding of less than $25,000.00.

Where the monetary penalty bears no proportionate relationship to the number of false claims made, or to the damages sustained by the Government, the statute must be given close analysis. In *United States* v. *J.B. Williams Co.*, 498 F.2d 414 (2d Cir. 1974), defendants were fined under a civil penalty statute for violation of a final Federal Trade Commission order to cease and desist from certain conduct. The statute provided for a maximum penalty of $5,000.00 for each violation of the order. *Id.* at 418, n.1. The complaint alleged 100 violations and the computed penalty was $500,000.00 against each defendant. *Id.* The penalty-to-violation ratio was one-to-one.

B. THE CMPAA IS UNCONSTITUTIONAL AS APPLIED TO PETITIONERS

Under the facts and circumstances of the proceeding brought against petitioners, the penalties and assessments imposed are clearly not remedial, civil penalties, limited to the goal of restitution. The central issue underlying the charges against Dr. and Mrs. Mayers were 307 filed Medicare claim forms which totalled, in the aggregate, $145,550.00. There were allegedly 2,702 discrete items and/or services listed in the 307 claim forms filed, by which the $2,000.00 statutory maximum was multiplied, for a potential maximum liability of $5,404,000.00 on this branch of the sanctions alone, and an additional $291,100.00 assessment. However, payments made by Medicare's carrier on those claims only amounted to $24,697.73, which sum the Government has subsequently recouped in full. Such sums do not constitute restitution when the payments made by Medicare on the specific claims at issue resulted in a judgment more than seventy (70) times in *excess* of the sum allegedly falsely collected, above and beyond that already recouped by HHS. Such penalties go far beyond indemnifying the Government for its losses.

C. BECAUSE THE CMPAA IS, AT BEST, A QUASI-CRIMINAL STATUTE, PROOF OF FRAUDULENT INTENT MUST BE ESTABLISHED

Based on the intent of Congress to punish fraud, and the severity of the penalty, the CMPAA is a quasi-criminal statute to which

appropriate constitutional protections must apply. In order to establish liability under the CMPAA, proof must be established that a provider presented a claim knowing it to be materially false and fraudulent, and intending to cheat and/or to deceive the Government through its reliance upon material misrepresentations. Proof must be established that the provider had "guilty knowledge," "deliberately" presented the fraudulent claim, and/or had "actual knowledge" of its fraudulent nature. *See United States* v. *Nill*, 518 F.2d 793, 800 (5th Cir. 1975).

Forfeitures and penalties as severe as those authorized and imposed under the CMPAA are quasi-criminal; they necessitate the constitutional protections common to criminal proceedings, irrespective of the proceeding's civil label or form. *Boyd* v. *United States*, 116 U.S. 616 (1886). In *Boyd*, a civil fraud action, the Court held that because the nature of the action was quasi-criminal the defendant was entitled to all of his Fourth and Fifth Amendment protections, even though the proceeding was civil in form. *Id.* at 634. A quasi-criminal statute or penalty triggers constitutional protections afforded defendants in criminal proceedings. The Court explained:

> It may be that it is the obnoxious thing in its mildest and least repulsive form; but illegitimate unconstitutional practices get their first footing in that way, namely, by silent approaches and slight deviations from legal modes of procedure. This can only be obviated by adhering to the rule that *constitutional provisions for the security of person and property should be liberally construed*. A close and literal construction deprives them of hold their efficacy, and leads to gradual depreciation of the right, as if it consisted more in sound than in substance. *It is the duty of courts to be watchful for the constitutional rights of the citizen, and against any stealthy encroachments thereon*. *Id.* at 635 (emphasis added).

Likewise, in *United States* v. *Ward*, 448 U.S. 242, *reh'g denied*, 448 U.S. 916 (1980), the Court recognized that even were it to be determined that a statute would not be stricken on constitutional grounds, it is incumbent upon the Court to analyze the

statute in terms of its quasi-criminal nature or effect. *See also Kennedy* v. *Mendoza-Martinez*, 372 U.S. 144 (1963).

D. THE CMPAA IMPERMISSIBLY INFRINGES ON THE CONSTITUTIONAL RIGHT TO CONTRACT

This Court has held that the Constitution protects an individual's right to pursue the occupation of his choice under the Fifth Amendment, and the individual's freedom of association under the First Amendment. *See, e.g., United States* v. *Robel*, 389 U.S. 258, 263-65 (1967). These same rights are protected by the Fourteenth Amendment. *Meyer* v. *Nebraska*, 262 U.S. 390, 399 (1923). The Fifth Circuit has held that the Fourteenth Amendment protects and enforces the individual's freedom to contract for and practice a desired occupation.

> Liberty . . . extends to the full range of conduct which the individual is free to pursue. . . . Contemplated within this term is the right to practice any of the common occupations of life, and for others to engage the individual to perform those acts which are his occupation. These rights are within the Fourteenth Amendment.

Shaw v. *Hospital Authority of Cobb County*, 507 F.2d 625, 628 (5th Cir. 1975) (citations omitted).

The Eleventh Circuit found that in order for items and services to be reimbursed as an "incident to" a physician's care, those services must be (1) ordered by the physician seeking reimbursement, (2) supervised by that same physician, and (3) rendered by personnel employed by the ordering and supervising physician, and that "supervision" mandates direct personal supervision, *to wit*, presence in the office suite at a distance no farther than the next room. This holding directly and irrationally conflicts with the constitutional rights of providers to pursue the employment of their choice.

The Eleventh Circuit's construction of the CMPAA does more than seek to effectuate reasonable regulation of the business practices of Medicare providers in order to protect the credibility and

financial stability of the Medicare program. The Court of Appeals effectively annihilates the legality of professional associations within a clinic setting; discourages the interaction of medical doctors and doctors of chiropractic; and restricts the time and cost efficient use of ancillary personnel, unless personally employed by the physician, to the point of reducing the constitutional right to employment to a mere nullity. In essence, it prohibits physicians of all trainings from becoming employed by an independent third party entity, which employs assistants and other personnel to help in the administration of healthcare, rendering or ordering the furnishing of services to patients, and seeking reimbursement for services, except in the limited instance when the physician is the ordering and supervising physician, and when he personally employs the ancillary personnel rendering the services. Further, it renders illegal the common practice of physicians "covering" for one another. Lastly, it renders meaningless the use of ancillary personnel – a time and cost efficient component of healthcare today – because it requires the physician's presence and direct supervision.[20] Thus, the Eleventh Circuit's construction of the Medicare statute, specifically its determination of the requirements for reimbursement of services rendered as an "incident to" a physician's care, impermissibly conflicts with the constitutional rights of "physicians."

There is nothing illegal nor impermissible about the formation of professional organizations, as between physicians; nor is there anything improper about structuring a practice such that physicians share professional responsibilities with other licensed and skilled physicians. Yet, the Eleventh Circuit's interpretation of "incident to" has otherwise prohibited these types of associations and subjects a provider to massive and severe sanctions. It has done so although the statute gives no notice that such relationships are illegal. In view of the fact that the Medicare statute fails to define "incident to" for purposes of explaining the circumstances under which ancillary services may be reimbursed, and that it does not even contain the word "supervision," Congress' exercise of its legislative authority to enact the Medicare

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[20] In effect, when the physician is called away on an emergency, or is at lunch, down the hall, in the rest room, or in another part of the building, the rendition of ancillary services must come to a halt.

Act, if the Act is to be construed as restrictively as the Eleventh Circuit suggests, is improper, and the CMPAA penalty and assessment must fall.

III

THE DECISION BELOW WILL OBSTRUCT THE EFFICIENT AND UNIFORM ADMINISTRATION OF THE FEDERAL MEDICARE PROGRAM; THE NATIONAL INTEREST FAVORS SUPREME COURT REVIEW OF THE CMPAA

Throughout the United States, medicare providers provide quality, low-cost healthcare to approximately 31 million eligible Medicare beneficiaries. N.Y. Times, Feb. 12, 1987, at D1, col. 6. Since its creation in 1965, the Medicare program[21] has continued to grow and develop. Because of its magnitude and scope, administration of the Medicare program and, by extension, the CMPAA, is of crucial interest and importance to the welfare of the general public.[22] Indeed, since its enactment in 1981, and its initial implementation in 1983, HHS has applied the CMPAA to over 250 providers nationwide. 1 CMPR Newsl. 1, 8 (No. 1, Nov. 1986). Over $27 million in payments have been demanded as a result of settlements or the imposition of penalties and assessments pursuant to the statute.[23] *Id.*

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[21] Recent amendments modify Medicare appeal rights to allow Part B beneficiaries to seek judicial review of the carrier's determination with respect to their Part B claims, and to allow providers to represent beneficiaries on these appeals. Omnibus Budget Reconciliation Act of 1986 ("OBRA"), Pub. L. No. 99-509, 100 Stat. 2008. *See generally* H.R. Con. Rep. No. 5300, [No. 505 Extra Edition] Medicare & Medicaid Guide (CCH) (Nov. 4, 1986) [hereinafter H.R. Con. Rep. No. 5300].

[22] The imposition of civil money penalties has become an important issue in the legal community. The complexity of the Medicare statutes and regulations have transformed CMPAA litigation into an area of legal specialty and expertise. A new, quarterly publication, Civil Money Penalties Reporter: Medicare-/Medicaid Fraud & Abuse, updates the current status of the CMPAA, its implementing regulations, and cases arising thereunder.

[23] Notably the earlier trend in CMPAA cases to reach settlement with the Inspector General prior to any formal service of a notice of intent to impose civil money penalties is changing. Of the more than 250 CMPAA related cases, 30

(Footnote Continued)

Although this is the first case to challenge the constitutionality of the CMPAA in its entirety, the Court of Appeals for the Fifth Circuit in *Griffon* v. *Bowen*, 802 F.2d 146 (5th Cir. 1986), recently held that because the CMPAA substantively affects the rights of individuals, it could not constitutionally be applied retroactively. The Secretary's decision to impose civil money penalties was vacated. It is apparent that healthcare providers are no longer subjecting themselves to hugh sanctions without seeking full adjudication of their rights. Consequently, litigation as to the propriety of the measured sanctions and the constitutionality of the statute will continue to flourish.

The Eleventh Circuit's decision upholding the constitutionality of the CMPAA creates new law critically affecting the immediate rights and obligations of individual providers *and* beneficiaries nationwide. The Eleventh Circuit's decision is in violation of the constitutional rights of providers, by permitting the Secretary to issue requirements for reimbursement – specifically, for services provided as an "incident to" a physician's care – in a Carriers Manual and on the back of a claim form, and to hold providers liable for massive penalties and suspension from the Medicare program when they violate these requirements, although no similar requirements are set forth in the statute or

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have resulted in a formal proceeding against the provider. The others, presumably, have been settled. Interestingly, of the 30 in which a formal notice of intent to impose civil money penalties has been issued, almost half have been settled prior to administrative determination. The remaining 15 or so cases exhaust the administrative remedies and then either succumb to the Secretary's demands or pursue judicial review in their respective Courts of Appeals, as occurred here. *See* 1 CMPR Newsl. at 8 (No. 1). The number of CMPAA challenges is likely to increase substantially as a consequence of the 1986 OBRA Amendments. These Amendments extend the civil money penalty provisions of the CMPAA to non-participating physicians who fail to meet certain disclosure requirements or collect for medically unnecessary services, to hospitals and/or HMOs or CMPs which offer or accept indirect payments as incentives to limit or reduce services provided to beneficiaries, to certified registered nurse anesthetists or physician assistants who seek reimbursement for Medicare services in excess of the permitted rates, and to HMOs and CMPs which fail to provide medically necessary care to beneficiaries. *See generally* H.R. Con. Rep. No. 5300, *supra*.

regulations.[24] The Administrative Procedures Act demands that legislative rules, substantially affecting the rights and obligations of parties, be published in the Federal Register and debated.[25] 5 U.S.C. § 553 (1977).

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[24] Although the Eleventh Circuit found that the CMPAA and its implementing regulations are clear and unambiguous as to the services properly reimbursable to a chiropractor, and clear and unambiguous in defining the conditions pursuant to which services are reimbursable as an "incident to" a physician's professional care, the Court does not make a *single* citation to the statute or regulations setting forth the meaning of "incident to" or the requirement that direct personal "supervision," meaning no farther than the next room, is required as a necessary condition to reimbursement. Instead, the Court relied on the back of a claim form as sufficient evidence that the statute put petitioners on notice that their conduct violated the law. One court has found that the claim form prepared and issued by HHS is "ambiguous and 'grossly inadequate' to reflect the services and the manner in which they [are] rendered." *United States* v. *Mir*, Case. No. 86-5005 [Report No. 518] Medicare & Medicaid Guide (CCH) 8 (9th Cir. Mar. 3, 1987).

[25] The substantive requirements and conditions for the reimbursement of services rendered as an "incident to" a physician's care are also contained in the Carriers Manual distributed only to intermediaries and carriers, and *not* to providers.

> The Carrier's Manual is a compilation of instructions prepared and periodically revised by the Secretary *for circulation to private insurance carriers* charged with computing and paying Part B claims in conformity with the [Medicare] Act . . . [T]he Carrier's Manual is not published in the Federal Register or the Code of Federal Regulations.

Linoz v. *Heckler*, 800 F.2d 871, 878, n.2 (9th Cir. 1986). *See also Schweiker* v. *Hanson*, 450 U.S. 785 (1981), *reh'g denied*, 451 U.S. 1032 (1982). In *Linoz*, the Ninth Circuit struck down a portion of the Carriers Manual which set forth the conditions for reimbursement of certain services because the Manual provision was not published in the Federal Regulations or promulgated in compliance with the APA. *Id.* at 877-88. *See also, American Hosp. Ass'n* v. *Bowen*, Case No. 85-0311 [New Developments] 1986 Medicare & Medicaid Guide (CCH) 35, 425 (D.D.C. May 30, 1986). This Court itself has held that Carriers Manual provisions are not law and, not binding. *Hanson*, 450 U.S. at 789. Although the Eleventh Circuit does not expressly refer to the Carriers Manual, the Carriers Manual provision was heavily cited in the Briefs submitted to the Eleventh Circuit.

The practical effect of the Eleventh Circuit's decision is that providers will decide simply not to participate in the Medicare program. *See, e.g., Duggan* v. *Bowen*, Case No. 87-0383 [Report No. 518] 1987 Medicare & Medicaid Guide (CCH).[26] Legal practitioners and scholars are unable to counsel those seeking advice as to whether their conduct will subject them to massive sanctions and a suspension, and are unwilling to advise about a particular court's outcome in light of the decision in *Mayers*.

A determination as to the statute's constitutionality will have an immediate and broad impact on the rights of healthcare providers and beneficiaries throughout the nation. Inevitably, this Court's determination of the constitutionality of the CMPAA will shape the manner in which this national program of healthcare insurance is administered, the rights and obligations of providers *and* beneficiaries involved therein, and the overall future of the federal program, all of which are issues of great federal concern. This Court should recognize and determine, as it has in the past, "the importance of the issue for the [healthcare] community and for the administration of the [Medicare] laws," and grant petitioners a writ of certiorari to determine the constitutionality of the CMPAA. *See, e.g., National Broiler Mktg. Ass'n* v. *United States*, 436 U.S. 816 (1978).

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[26] As one Court has recognized, providers are important to the success of the Medicare program.

> The [Medicare and Medicaid] program[s], to be effective, must be sufficiently attractive to enlist providers so that services are available to [beneficiaries]. It follows, therefore, that if the rates are not adequate, services will not be provided, thus both the provider and the recipient's will be adversely affected.

Dental Soc'y of New York v. *Carey*, 92 A.D.2d 263, 461 N.Y.S.2d 77, (3d Dep't 1983).

CONCLUSION

For all of the foregoing reasons, petitioners respectfully submit that a writ of certiorari should be issued.[27]

Respectfully submitted,

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[27] In the alternative, in light of the Secretary's admission in *Inspector General* v. *Silver*, this Court should reverse and remand this case to the Court of Appeals with instructions that that Court remand to the Secretary for further proceedings consistent with the Secretary's decision in *Inspector General* v. *Silver*.

APPENDIX

William J. MAYERS, D.C. and Patricia M. Mayers, Petitioners,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.

No. 85-3803.

United States Court of Appeals, Eleventh Circuit.

Dec. 22, 1986.

Chiropractor and bookkeeper appealed from administration determination of the Secretary of Health and Human Services determining that Civil Monetary Penalties and Assessment Act is constitutional on its face and as applied. The Court of Appeals, Hill, Circuit Judge, held that: (1) Civil Monetary Penalties and Assessment Act, which provides for $2,000 civil penalty for each item falsely claimed in medicare billing, is civil in nature, and thus, proceedings under Act are constitutionally adequate, and (2) penalty assessed against chiropractor of $1,791,100, based on receipt of $24,697.73 from medicare program for false claims, was warranted by aggravating circumstances.

Decision enforced.

1. Penalties — 16

In determining whether penalty imposed by particular statute is civil or criminal in nature, first inquiry is whether Congress expressly or impliedly designated statute as civil or criminal, and second prong of inquiry is whether statute is so punitive either in purpose or effect as to negate intention of Congress.

2. Constitutional Law — 278.7(3)

Social Security anad Public Welfare — 18

Civil Monetary Penalties and Assessment Act, which provides for $2,000 civil penalty for each item falsely claimed in medicare billing, is civil in nature, and thus, proceedings under Act are

constitutionally adequate, even though penalty is based on amount claimed rather than actual loss sutained by Government. Social Security Act, § 1128A, as amended, 42 U.S.C.A. § 1320a-7a.

3. Social Security and Public Welfare — 18

Penalty assessed against chiropractor of $1,791,100 under the Civil Monetary Penalties and Assessment Act, based on receipt of $24,697.73 from medicare program for false claims, was warranted by aggravating circumstances, including fraudulent request for payment of 2,702 items, fact that such claims were but small part of larger pattern of activity, and claimant's attempt to deceive investigators by fabricating documents during course of investigation. Social Security Act, § 1128A, as amended, 42 U.S.C.A. § 1320a-7a.

4. Social Security and Public Welfare — 18

Actual knowledge of filing of false medicare claims is not required for imposition of liability under the Civil Monetary Penalties and Assessment Act, which specifically provides for liability if "person knows or has reason to know" that medical item or service was not provided as claimed. Social Security Act, § 1128A, as amended, 42 U.S.C.A. § 1320a-7a.

5. Social Security and Public Welfare — 18

Civil Monetary Penalties and Assessment Act, authorizing imposition of $2,000 fine for each false item submitted for medicare reimbursement, placed chiropractor and bookkeeper on notice that their conducted violation the Act, and thus, Act and its implementing regulations were not unconstitutionally vague and ambiguous, in light of provision in Social Security Act that chiropractor's services are not routinely covered. Social Security Act, §§ 1 et seq., 1128A, 1861(r), as amended, 42 U.S.C.A. §§ 301 et seq., 1320a-7a, 1395x(r).

Laurence B. Liebowitz, Liebowitz & Royster, P.C., Elmsford, N.Y., for petitioners.

John C. Hoyle, U.S. Dept. of Justice, Civil Div., Appellate Staff, Washington, D.C., for respondent.

Petition for Review of an Order of the U.S. Department of Health and Human Services (Florida Case).

Before HILL and FAY, Circuit Judges, and MORGAN, Senior Circuit Judge.

HILL, Circuit Judge:

In this appeal from an administrative determination of the Secretary of Health and Human Services the constitutionality of the Civil Monetary Penalties and Assessment Act (CMPAA), 42 U.S.C. § 1320a-7a (1982 & Supp. III 1985) is challenged. We hold this statute to be constitutional on its face and as applied to the petitioner. Petitioner raises several additional challenges to the assessment of a civil penalty by the Administrative Law Judge. These attacks on the Administrative Law Judge's decision are also rejected.

This action was commenced by the United States Department of Health and Human Services to recover civil penalties for 307 false medicare claims for reimbursement filed by William Mayers, a chiropractor, operating three chiropractic centers in the Fort Meyers, Florida area. Mayers was assisted in this scheme by his wife, Patricia, who handled the bookkeeping for the clinics. The 307 claims contested by the Department covered 2,702 false items and services for which the Mayers sought reimbursement in the amount of $145,550.

The Administrative Law Judge who heard this matter found that the Mayers knew or should have known that the 2,702 items and services were not provided as claimed. The Administrative Law Judge proceeded to impose an assessment and civil penalty of $1,791,100 and ordered the Mayers suspended from the

Medicare and Medicaid programs for 25 years. The decision was affirmed by the Secretary of the Department of Health and Human Services.

The CMPAA was added to the Social Security Act to discourage fraud in the Medicare program. Specifically, the Act authorizes the Secretary of the Department of Health and Human Services to impose a $2,000 fine for each item submitted for reimbursement when the person submitting the claim knew or should have known the item was not provided as claimed. 42 U.S.C. § 1320a-7a (1982 & Supp. III 1985). In addition to the fine, the Act permits "an assessment of not more than twice the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim." *Id.* Finally, the Act authorizes the Secretary to bar an individual from participating in the Medicare program from filing a false claim. *Id.* § 1320a-7a(b).

The establishment and administration of Medicare is set forth in subchapter XVIII of the Social Security Act. Essentially, the medicare program consists of three parts: (1) Part A concerns insurance for hospital and related post-hospital services for eligible beneficiaries (42 U.S.C. §§ 1395c to 1395i-2); (2) Part B concerns supplemental insurance covering various health services for eligible beneficiaries not included within Part A (42 U.S.C. §§ 1395k-1395w); (3) Part C sets forth miscellaneous provisions not covered in Parts A and B (42 U.S.C. §§ 1395x-1395xx). All claims submitted by the Mayers are governed by Part B of the Medicare Program.

Part B specifically covers "medical and other health services" rendered to eligible beneficiaries. 42 U.S.C. § 1395k(a)(1) (1982). "Medical and other health services" are defined so as to include physicians' services, services and supplies "furnished as an incident to a physician's professional service," and diagnostic tests. *Id* § 1395x(s). The Act further defines physician's services as "professional services performed by physicians." *Id.* § 1395x(g). Chiropractors are included in the definition of physician "only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation demonstrated

by X-ray to exist)." *Id.* § 1395x(r). None of the claims filed by the Mayers were for services included within this very narrow category.

The evidence presented to the Administrative Law Judge supports the conclusion that: (1) the Mayers operated a clinic designed solely to provide chiropractic services; (2) the services rendered at the clinic were clearly not reimbursable under Medicare, and (3) the Mayers engaged in a fraudulent scheme to disguise these non-reimbursable chiropractic services as services rendered by a physician. As part of this fraudulent scheme, the Mayers placed various physicians on the clinic's payroll and claimed these physicians were in charge of the treatment of patients. This was done so that the chiropractic services rendered by the clinic would have the appearance of being rendered incident to a physician's service. In fact, such was not the case.

The physicians hired by the clinic were retained for the sole purpose of lending their names and licenses to the clinic's claims for Medicare reimbursement. The doctors hired by the clinic knew little about chiropractic treatment prior to their employment. Once hired, these doctors had little contact with the patients of the clinic. All patients treated by the clinic received essentially the same tests and therapies. Due to the standardized nature of the chiropractic services, the physicians played no role in the administration of this treatment.

William Mayer's conduct underscores the fact that these doctors were hired for the sole purpose of obtaining the Medicare billing numbers of the physicians. Prior to hiring these doctors, mayer told his wife: "The best thing to do would be to get a foreign doctor, someone that doesn't understand the language too well or speak it too well to sign [Medicare claims]." The Mayers proceeded to hire three doctors of foreign extraction. These doctors were required to permit a rubber stamp to be made of their signature to facilitate Medicare billing. Although such a rubber stamp is not improper when used in the preparation of a valid claim, here the Mayers acquired these rubber stamps to perpetuate their fraudulent scheme. Although a

Medicare carrier informed the Mayers that the use of such rubber stamps would not be permitted, the Mayers continued this practice. Despite efforts by the physicians to gain custody of the stamps upon departing from the Mayers' employment, the Mayers routinely retained at least one stamp of each doctor's signature. These rubber stamps were used by the clinic in preparing Medicare claims for services rendered after the doctors had left the clinic. Of the 2,702 items contested by the Secretary in this action, the physicians hired by the Mayers were either not present at the office or not currently in the Mayer's employment at the time the services were rendered.

I. CONSTITUTIONALITY OF THE CMPAA

If the CMPAA is deemed to be a criminal statute, the proceedings against the Mayers would have been constitutionally inadequate. We therefore must consider whether the penalty imposed was civil or criminal in nature.

[1] In determining whether a particular statute is civil or criminal in nature, a two prong inquiry is utilized. *United States v. Ward*, 448 U.S. 242, 248-49, 100 S.Ct. 2636, 2641, 65 L.Ed.2d 742 (1980). The first inquiry is whether Congress has expressly or impliedly designated the statute as civil or criminal. The Mayers argue that the legislative intent in enacting the CMPAA was to provide the government with an alternative means of prosecuting Medicare/Medicaid fraud cases. Citation is made to numerous legislative reports in support of this argument. *E.g.*, H.R.Rep. No. 158, 97th Cong., 1st Sess., vol. III, at 329 (1981) ("The civil monetary penalty provided for in this bill is intended to provide an alternative to criminal proceedings so as to increase the effectiveness of enforcement in the medicare and medicaid programs."). The clear congressional intention, however, is that the alternative to prosecution is to be a *civil* proceeding. As in *United States v. Ward*, U.S. 242, 100 S.Ct. 2636, 65 L.Ed.2d 742 (1980), the labeling of the sanction as a "civil penalty" is determinative of Congressional intent. This is particularly true in light of the name given by Congress to the act – the *Civil* Monetary Penalties & Assessment Act.

[2] The second prong of the inquiry is whether the statute is "so punitive either in purpose or effect as to negate [the intention of Congress]." *Ward*, 448 U.S. at 249, 100 S.Ct. at 2641. Rarely will a court find a statute to be criminal in nature when Congress has exhibited an intent to impose civil sanctions: "[O]nly the clearest proof could suffice to establish the unconstitutionality of a statute on such a ground." *Flemming v. Nestor*, 363 U.S. 603, 617, 80 S.Ct. 1367, 1376, 4 L.Ed.2d 1435 (1960). The issue to be addressed by this court is whether the sanctions are so severe that the excessive nature of the penalty has "transformed what was clearly intended as a civil remedy into a criminal penalty." *Rex Trailer Co. v. United States*, 350 U.S. 148, 154, 76 S.Ct. 219, 222, 100 L.Ed. 149 (1956).

The Mayers' argument that the CMPAA is criminal in nature is primarily based on two aspects of the act. First, the CMPAA provides for a $2,000 civil penalty for *each* item falsely claimed. It is contended that such a penalty based upon individual line items rather than the total claim is so excessive as to constitute a criminal penalty. Second, appellants emphasize that the penalty is based on the amount claimed rather than the actual loss sustained by the government. Such a process, it is argued, is designed to exact retribution rather than restitution.

We find this argument unpersuasive. Numerous statutes which exact heavy civil penalties have been held constitutional. *See, e.g., Rex Trailer Co., Inc. v. United States*, 350 U.S. 148, 76 S.Ct. 219, 100 L.Ed. 149 (1956) ($2,000 penalty per fraudulent act permissible under Surplus Property Act of 1944); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (False Claims Act). Just as these acts have been found to be permissible civil penalties, neither does the CMPAA violate the mandate of the constitution.

The basic premise of appellant's argument is that the civil penalty grossly exceeds the damages sustained by the government. Such a presumption is incorrect. The costs which fraud has placed upon our nation's Medicare and Medicaid programs have been severe. *See* Kusserow, *Civil Money Penalties Law of 1981: A New Effort to Confront Fraud and Abuse in Federal*

Health Care Programs, 58 Notre Dame L.Rev. 985 (1983). it has been estimated that as much as ten percent of federal funds allocated to health care programs may be lost each year to fraudulent claims. *Id.* at 985 n. 1. The cost of investigating and prosecuting such fraudulent claims has been extremely costly as well. Appellant is correct that the civil penalty imposed does exceed the amount that was directly disbursed as a result of the defendants' fraudulent conduct. Appellant, however, fails to recognize that each fraudulent claim filed exacts an immense toll from society. Just as punitive damages in tort law or treble damages under antitrust law encompass a civil remedy in excess of the tangible damages sustained by a plaintiff, here the government has made a determination that activities in violation of the CMPAA result in damages in excess of the actual amount disbursed by the government to the fraudulent claimant. Such a legislative determination is not constitutionally infirm.

[3] Additionally, it is argued that the CMPAA is unconstitutional as applied to the Mayers. The Mayers sought reimbursement in the amount of $145,550 for the fraudulent items presented. The Mayers actually received a total of $24,697.73 from the Medicare program toward these claims. The penalty assessed against the Mayers was in the amount of $1,791,100.[1] Although the judgment imposed is seventy times greater than the amount actually collected from the medicare program for these false claims, the amount of the judgment does not result in an unconstitutional application of the CMPAA. The size of the penalty is a direct result of the defendants' conduct. The defendants chose fraudulently to request payment for 2,702 items. We also note that the aggravating circumstances in this case amply justify the award. Among numerous other aggravating circumstances, the Administrative Law Judge found that the 2,702 fraudulent claims were but a small part of a larger

[1] Under the CMPAA, the ALJ could have imposed a civil penalty of $5,404,000 based on the 2,702 items fraudulently claimed. The ALJ, however, determined that an award of $1,791,000 would be sufficient to protect the government's interest.

pattern of activity. Furthermore, the Mayers attempted to deceive investigators by fabricating documents during the course of the investigation. In light of the Mayers' conduct, the civil penalty imposed by the Administrative Law Judge was proper.

II. OTHER CLAIMS RAISED BY APPELLANT

[4] The administrative law judge found that Mayers knew or should have known that the claims filed contained false information. The CMPAA specifically provides for liability if a "person knows or has reason to know [that a medical item or service] was not provided as claimed." 42 U.S.C. § 1320-7a(a)(1)(A) (1982). In spite of the clear wording of the statute, appellant contends that actual knowledge must be established to impose liability under the CMPAA. Appellant fails to cite any authority indicating that a more rigorous standard is constitutionally required before imposing a civil penalty. A *criminal* statute may constitutionally impose a fine or imprisonment based upon a defendant's negligent conduct. The Mayers, however, argue that a *civil* penalty may not be imposed where they knew or should have known that their conduct was wrongful. Such an argument must be rejected.

[5] Appellants contend that the CMPAA and its implementing regulations are vague and ambiguous. Essentially, it is argued that one could reasonably interpret the definition of "physician" under the Social Security Act to encompass a chiropractor. Therefore, appellants conclude that the act fails to place them on reasonable notice that their conduct violated the CMPAA.

The Administrative Law Judge properly concluded that the Mayers were put on notice that their conduct violated the CMPAA. Each claim form submitted by the Mayers contained the following printed provision:

> For services to be considered incident to a physician's professional service, (1) they must be rendered under the physician's immediate personal supervision by his/her employee, (2) they must be an integral,

> although incidental part of a covered physician's service, (3) they must be of kinds commonly furnished in physicians' offices, and (4) the services of non-physicians must be included on the physician's bills.

The Social Security Act unambiguously provides that a chiropractor's services are not routinely covered. Such services are covered "only with respect to treatment by means of manual manipulation of the spine (to correct a sublaxation demonstrated by X-ray to exist) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided." 42 U.S.C. § 1395x(r) (1982). In light of the explicit detail in which Congress narrowly defined reimbursable chiropractic services, no individual could reasonably conclude that other services performed by a Doctor of Chiropractic medicine would be reimbursable.

The record shows that the Mayers engaged in an elaborate scheme of hiring physicians of foreign extraction for no purpose other than to obtain medicare billing numbers. The Administrative Law Judge found that the Mayers would not have done so if they honestly believed all chiropractic services were reimbursable. The record makes it clear that the Mayers continued to rubber stamp the signatures of physicians to Medicare claims during periods when the physicians were no longer employed. The Mayers intentionally prepared post-dated physicians orders after the Medicare investigation was begun. This effort to camouflage their path further refutes their assertion that they believed that all chiropractic services were covered by the Social Security Act.

The Mayers additionally claim that the Department of Health and Human Services failed to respond to their inquiry concerning the propriety of their conduct. This claim is without merit. The Mayers were specifically advised that services had to be ordered and supervised by a medical doctor for such services to be reimbursable.

The Administrative Law Judge heard nearly two weeks of testimony detailing the Mayers fraudulent conduct. The government entered into evidence 480 written exhibits at the Mayers' hearing. In spite of the voluminous record supporting each element of the Administrative Law Judge's decision, the Mayers argue that the determination was not supported by substantial evidence and was arbitrary and capricious. This claim is without merit.

Also without merit is appellant's argument that the Administrative Law Judge acted improperly by hearing evidence beyond the scope of the claims alleged by the government. The Administrative Law Judge properly heard evidence of aggravating facts in order to determine appropriate damages.

For the foregoing reasons, the decision of the Department of Health and Human Services is

ENFORCED.

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-3803

WILLIAM J. MAYERS, D.C. and PATRICIA M. MAYERS,

Petitioners,

versus

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Petition for Review of an Order of the
U.S. Department of Health and Human Services

ON PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC

(Opinion Dec. 22, 1986, 11 Cir., 198__, _____F.2d_____).

(February 26, 1987)

Before HILL and FAY, Circuit Judges, and MORGAN, Senior Circuit Judge.

PER CURIAM:

(✓) The Petition for Rehearing is DENIED and no member of this panel nor Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 26), the Suggestion for Rehearing En Banc is DENIED.

( ) The Petition for Rehearing is DENIED and the Court having been polled at the request of one of the members of the Court and a majority of the Circuit Judges who are in regular active service not having voted in favor of it (Rule 35, Federal Rules of Appelate Procedure; Eleventh Circuit Rule 26), the Suggestion for Reharing En Banc is also DENIED.

( ) A member of the Court in active service having requested a poll on the reconsideration of this cause en banc, and a majority of the judges in active service not having voted in favor of it, rehearing en banc is DENIED.

ENTERED FOR THE COURT:

/s/ James C. Hill
United States Circuit Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of: William J. Mayers, D.C., and Patricia M. Mayers, Respondents.	DGAB Doc. No. C-5 August 11, 1985

FINAL DECISION

This is a civil monetary penalties and assessments case under section 1128A of the Social Security Act for which review has been requested of the initial decision of the Administrative Law Judge. Section 1128A[1] authorizes the Secretary of Health and Human Services to impose civil monetary penalties and assessments against any person who makes false or other improper claims under certain Departmental health care reimbursement programs, principally Medicare and Medicaid. The Department's regulations[2] assign to the Inspector General the principal implementation responsibility for this authority, provide respondents with a right to a hearing before an Administrative Law Judge (ALJ), and provide for discretionary administrative review of ALJ decisions. This review authority was subsequently delegated to the Under Secretary.

This case involves William J. Mayers, a chiropractor, and his wife, Patricia Mayers, the operators of health care clinics in the vicinity of Fort Myers, Florida. The Inspector General alleged that from June 1982 through January 1984, the respondents submitted claims for Medicare reimbursement for

[1] 42 U.S.C. 1320a-7a.

[2] 45 C.F.R. Part 101, 48 Fed. Reg. 38,827, *et seq.* (August 26, 1983).

2,702 medical items or services which they falsely represented as having been provided by licensed physicians. These claims were for an amount of $145,550. The Inspector General proposed the imposition of aggregate penalties and assessments of $2,900,000. The respondents exercised their right to a hearing, which was presided over by Administrative Law Judge Steven T. Kessel. After a lengthy hearing and the accumulation of a substantial record, Judge Kessel issued, on May 14, 1985, an initial decision which imposed an assessment of $291,100 and a penalty of $1,500,000, and suspended the respondents from the Medicare program of a period of 25 years. Thereafter, the respondents filed timely exceptions, which are opposed by the Inspector General. Review is hereby granted.

The conduct of the respondents, as found by the ALJ, can only be characterized as an extremely flagrant abuse of the Medicare program. Medicare Part B health insurance benefits pay for a very broad range of services provided by licensed physicians, including not only services personally rendered by a physician, but also services provided by other medical professionals that are incident to the physician's services and are ordered and personally supervised by the physician. Medicare also reimburses for a very limited category of medical services provided by chiropractors. The ALJ found that the respondents developed and implemented a method of operation under which they provided to many Medicare patients chiropractic services that the respondents knew were not reimbursable under Medicare, but misrepresented them as being ordered and supervised by a licensed physician incident to the provision of medical services provided by that physician. To accomplish this, the respondents hired a series of three physicians, had rubber stamp likenesses made of the physicians' signatures, and then used the stamps to certify Medicare claim documents to claim reimbursement for physician services in which, in fact, the physicians had no real involvement. So mechanized was this method of operation, according to the ALJ's findings, that these rubber stamps were used during significant periods after the respective physicians left the employ of the respondents.

The method of operation found by the ALJ to have been in existence suggests that generating Medicare claims was the principal function of the respondents' clinics. The physicians employed by the respondents typically performed routine physical examinations of new patients and prepared patient history forms, but for all practical purposes had no further relationship to the medical tests and therapies provided to the patients, which generally consisted of a standard regime of periodic x-rays and other tests and a standard series of chiropractic adjustments. The standard regimen of tests and treatments was established and supervised not by the physicians whose rubber stamp signatures appeared on the claim forms, but rather by Dr. Mayers. Under this method of operation, up to 170 patients per day were treated at one of the respondents' clinics and up to 250 patients per day at the other. The usual practice was for patients to visit the clinic several times per week to receive this standard series of tests and therapies.

The ALJ also found that the respondents billed Medicare for fees in excess of $1.8 million, attributed as services rendered by or incident to the services of the three physicians. The respondents were reimbursed in excess of $500,000 for these alleged services. The ALJ further found that the vast majority of items or services billed by respondents on the accounts of these physicians were not actually provided, ordered or supervised by these physicians, nor were they provided incident to services provided by them. Among these many claims were the 2,702 items or services for which the Inspector General sought to impose civil monetary penalties and assessments in this action. With respect to these items or services claimed, the ALJ found that the physician employees on whose accounts these items or services were claimed were not present at the clinics or were not employed by the respondents on the dates on which the services were allegedly rendered by those physicians. The ALJ found that these 2,702 items or services represented a small percentage of a much larger pattern of filing false claims for Medicare reimbursement.

In view of these findings, the ALJ found there to be substantial aggravating circumstances[3] regarding these false claims and imposed an assessment of $291,100, the maximum amount allowable, and a penalty of $1,500,000. He further suspended the respondents from the Medicare program for a period of 25 years.[4]

The respondents have filed a number of exceptions to the initial decision. Most significantly, they argue that various rules and instructions of the Medicare program do not make clear that the degree of involvement of the licensed physicians in patient care at respondents' clinics was insufficient to qualify for reimbursement as physician services. The respondents further assert that they did not receive a fair hearing and that various factors should have been considered in mitigation of the penalty, assessment and suspension.

All of the arguments raised by the respondents were fully addressed and persuasively rejected by the decision of Judge Kessel. Judge Kessel's findings are fully supported by the record. The record reflects that he provided the respondents a fair hearing, and that he fully considered the credibility or lack of credibility of the witnesses and documentary evidence presented. The

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[3] The ALJ's findings detail numerous other circumstances also considered aggravating. These included clear evidence that the respondents knew that their claims were false, that they ignored explicit advice from the Medicare Part B carrier that claims they were submitting were not reimbursable, that they attempted to deceive investigative authorities by preparing false documents to cover up the lack of involvement of licensed physicians in the tests and treatments provided, and that Dr. Mayers intentionally hired foreign-born physicians because he wanted physicians who could not understand English very well, but who could sign claims documents.

[4] At one point in the initial decision the ALJ stated that the period of suspension would begin May 3, 1984, the date the Inspector General initiated this action. Under the regulation, 45 C.F.R. §§ 101.105(b) and 101.125(f), the suspension period will begin when this decision comes final, as specified in § 101.125(f).

respondents' exceptions raise no credible basis to revise the findings in the initial decision or to reduce the amount of penalties and assessments or the period of suspension. Therefore, the respondents' exceptions are denied, and the initial decision is affirmed.

One issue in this case merits additional discussion. This is the matter of the amount of penalties and assessments imposed by the ALJ. The initial decision reflects that both the Inspector General and the ALJ believed the egregious circumstances in this case might have justified imposition of the maximum penalty and assessment. Under the statutory formula, the maximum penalty could have been $5,404,000, and the maximum assessment, an additional $291,100. However, both the Inspector General and the ALJ believed a lesser amount should be imposed to ensure consistency with the civil nature of the statutory authority and the concept that restitution and deterrence, but not retribution, are the objectives. The Inspector General noted this theme by referring to an internal guideline that generally limits aggregate penalties and assessments to $20 for each dollar falsely claimed, in this case $2,900,000.[5] Judge Kessell, although disinclined to adopt the Inspector General's internal guideline, decided to limit the penalty to $1,500,000 because this, in his view, represented a sufficient deterrent.

This is a subtle, but important issue. Both the Inspector General and the ALJ acted prudently and properly to factor in the restraining concept of civil liability. This factor, however,

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[5] This internal guideline, as explained by counsel for the Inspector General at the oral argument provided by the ALJ, was imprecisely summarized in the ALJ's initial decision at page 28, note 10. The ALJ's summary does not make clear that counsel described this guideline as generally *limitating* the aggregate penalties and assessments to 20 times the amount of the false claims in cases in which the maximum under the statutory formula is greater and there are substantial aggravating circumstances. This is quite different than the implication that this guideline is generally used to set the proposed civil liability.

should be considered in the totality of the circumstances of the case. Under the scope of the civil monetary penalty authority, these circumstances can vary widely, and can include situations where the Inspector General's purported internal guideline simply does not fit.[6] Tailoring the aggregate penalties and assessments amount to the totality of the circumstances eschews general reliance on a numerical multiple of any single factor, including the amount of the false claims.[7] Thus, Judge Kessel's disinclination to follow the Inspector General's internal guideline was quite understandable.

But further explanation of Judge Kessel's decision that a penalty of $1,500,000 was an adequate deterrence would have been helpful. Consideration of this question should include substantial attention to the magnitude of the offenders' wrongful conduct. In the present case, the ALJ found that the respondents

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[6] One of the only two other civil monetary penalties and assessments cases that have thus far been the subject of initial decisions by the ALJs is an example of a situation in which this internal guideline does not fit. In *In the Matter of George Griffon*, DGAB Doc. C-8 (May 15, 1985), a pharmacist falsely claimed Medicaid reimbursement at the rate allowed for brand-name drugs for 22 prescriptions actually filled with lower priced generic drugs. The ALJ in this case imposed liability of $44,000, the maximum penalty allowed, which was many times the amount falsely claimed in connection with the 22 prescriptions. Much more significant than the amount of the claims directly involved in the case was the fact that those 22 claims, all filed in a two-month period, represented just a tiny fraction of a much larger scheme that was found to have been in practice at least six years.

[7] In *In the Matter of Harold Chapman and Autumn Manor, Inc.*, DGAB Doc. No. C-5 (March 8, 1985), factors other than the amount of the false claims were also quite significant. One such factor was that because the amount of damages to the State agency was much less than the amount of the claims, liability under the False Claims Act would have been less than that permitted under the civil monetary penalties statute. Although in many cases, this would be a weighty factor, in that case it was not compelling because the offenders' fraudulent scheme was designed to obtain a much greater illegal windfall. This again underscores that it is the totality of the circumstances that must be the basis for the judgment.

had billed the Medicare program for more than $1,800,000. Other findings strongly indicate that not more than a tiny fraction of this amount was properly reimbursable and that virtually all of it was a function of the respondents' fraudulent scheme. In view of this factor, the ALJ's imposition of aggregate penalties and assessments of $1,791,100 approximates the magnitude of the fraudulent scheme and is entirely justifiable based on the totality of the circumstances established in the record.[8]

For these reasons, the initial decision is hereby affirmed.

8/11/5
Date

/s/ Charles D. Baker
Charles D. Baker
Under Secretary

[8] Additional points that might be pertinent to the application of the concept of civil liability limitations could include recognition of the apparent abuse of many Medicare patients who likely receive unnecessary tests and treatments, or possibly worse, in cases such as this. Also to be noted in considering notions of adequate deterrence is that in the past the presumed unlikelihood of getting caught at Medicare and Medicaid fraud has diminished the deterrent effect of available legal authorities, including criminal liability. Such matters were not developed in the record of this case. Refinement and application of these concepts are not easily accomplished, particularly in the context of this, only the third civil monetary penalties and assessments case to be heard by an ALJ. Although egregious circumstances such as those present in this case might well support aggregate liability higher than that imposed by Judge Kessel, it appears preferable at this point of experience under this statutory authority to aim toward further reflection and refinement by the Inspector General and Administrative Law Judges in future cases of this kind.

BEFORE THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Under Secretary

In the Matter of:

The Inspector General

v.

Frank P. Silver, M.D.,
Respondent.

DATE: April 27, 1987

Department Grant Appeals
Board Docket No. C-19

OPINION

On July 11, 1986, an administrative law judge ("ALJ") issued a Decision and Order finding Frank P. Silver, M.D. ("Respondent") liable under the Civil Monetary Penalty Law (CMPL), 42 U.S.C. §§ 1320a-7a(a)(1), 1320a-7(c), for filing 418 Medicaid claims for laboratory tests that were not provided as claimed. The Decision and Order imposed penalties of $232,000.00 and assessments of $9,237.59, and suspended Respondent from participating in the Medicaid and Medicare programs for a period of ten years. In so ruling, the ALJ concluded that although the Respondent did not intend to defraud or otherwise cheat the Medicaid program, he nevertheless was grossly negligent in not more carefully supervising the activities of his billing clerk and thus, he "should have known" that the billings being submitted to Medicaid by his billing clerk were erroneous. I granted Respondent's petition to review the Decision and Order of the ALJ in order to consider a number of significant issues directly bearing on the propriety of the ALJ's decision and the administration of the CMPL program, namely: (1) May an individual be held absolutely liable under the CMPL for the actions of an employee acting within the scope of employment; and (2) May an individual be subject to liability under the CMPL for his own negligent conduct.[1]

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[1] The parties in their briefs also addressed a third issue, namely: May an individual be subject to the maximum penalties under the CMPL if that individual's conduct is merely negligent, as opposed to intentional or reckless. In light of the decision reached below, that issue is no longer ripe.

For the reasons outlined below, I conclude (1) that an individual may not be subject to vicarious liability under the CMPL, but (2) that an individual may be subject to liability under the CMPL even though his conduct is merely negligent. However, I also conclude that the ALJ applied the incorrect standard in judging whether the Respondent's actions were negligent,[2] and that judged against the correct standard, the evidence adduced at the hearing falls short of sustaining the Inspector General's burden of proof. Accordingly, the Decision of the ALJ is reversed, the Order vacated and the case is remanded for further proceedings consistent with this Opinion and the attached Order.

I.

The Respondent is a licensed physician specializing in the practice of obstetrics and gynecology in Las Vegas, Nevada. Dr. Silver has practiced medicine in the Las Vegas area since 1973 and apparently is one of the few physicians who accepts Medicaid patients in the area.

This case arose under Section 1128A of the Social Security Act, (42 U.S.C. 1320a-7a), commonly referred to as the Civil Monetary Penalty Law (CMPL). The ALJ found that during the period August 13, 1981 through April 11, 1983, Respondent submitted 418 false or improper Medicaid claims for laboratory services in violation of the CMPL. It is therefore appropriate to discuss briefly the Medicaid program in the State of Nevada, the Respondent's office procedures and billing practices as they relate to laboratory tests and the history of the proceedings against the Respondent.

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[2] The Inspector General concedes that the ALJ used the incorrect standard in judging the Respondent's culpability under the CMPL. *See Inspector General's Brief Regarding Scope of Liability* 5 (filed February 6, 1987). However, the Inspector General maintains that the evidence introduced at the hearing is sufficient to establish liability under the correct standard.

A.

Title XIX of the Social Security Act, as amended (42 U.S.C. § 1396 *et. seq.*) established a system known as Medicaid under which the federal government provides financial assistance to participating states to aid them in furnishing medical care to needy persons. When a state chooses to participate in the Medicaid program, it must submit a State Plan to the Secretary of the Department of Health and Human Services ("DHHS") which meets federal statutory and regulatory requirements. The State Plan must provide for the designation of a single state agency to administer the Medicaid program.

Nevada's State Plan, which was approved by the Secretary, designated the Nevada Department of Human Resources (NDHR) to be the agency responsible for administering the Nevada Medicaid program. This program is referred to as "State Assistance for the Medically Indigent" or SAMI.

NDHR is responsible for determining eligibility for services, establishing standards for the services provided, establishing standards for submission of claims for reimbursements, setting payment levels for providers of services, and paying claims. To assist it in carrying out its responsibilities, NDHR contracted with Blue Shield of Nevada (BSN) to serve as fiscal intermediary for SAMI. In that capacity, BSN processed and paid claims submitted by Nevada providers for items or services which providers stated were rendered to Medicaid beneficiaries.

B.

Since 1973 and at all time relevant herein, Mrs. Kathleen J. Eby was employed as Respondent's bookkeeper. Respondent delegated to Mrs. Eby the responsibility of preparing Medicaid claims to be submitted to the SAMI program, signing the SAMI claims on behalf of Respondent, and filing those claims without Respondent's review. When SAMI forwarded payments to Respondent's office, Mrs. Eby would note on each patient's billing ledger the amount paid for each service claimed.

TR I/40.[3] In instances where SAMI or BSN did not pay, Mrs. Eby would contact the BSN provider service department and request an explanation. TR I/41. Respondent, used commercial laboratories to perform the analysis of specimens obtained from his patients (e.g. pap smears, vaginal and urine cultures, urinalysis and blood test). TR I/49,64, 74, III/519. Respondent's nurse would review a patient's medical chart and complete a test requisition form indicating the laboratory tests to be ordered from an outside laboratory. TR IV/524

The selected laboratory then sent a courier to Respondent's office to pick up the specimens and requisition forms. Test results were returned to Respondent's office, and if normal, placed on the patient's chart without review by Respondent. If the tests were abnormal, they would be shown to Respondent. Whenever Respondent was not shown a patient's test results, he assumed that the results were normal. TR III/524.

From about 1973 to 1983, the Respondent submitted Medicaid claims for laboratory services in three separate ways. TR I/71, 78. From 1973 to 1978, the Respondent performed all routine laboratory tests in his own office using a certified lab technician. I.G. Ex 425/1. The Respondent's laboratory, however, was not certified, as required by Nevada law. During this period Mrs. Eby would indicate on the Medicaid claim (item 22) that laboratory work was not performed outside the office.

In 1978 Respondent discontinued his office laboratory and instead paid an outside laboratory to perform the appropriate tests. This method was used by the Respondent until August 1981. The Respondent's claim forms submitted during this period indicated that an outside laboratory had performed the test, that Respondent had paid the laboratory for such services and that Respondent was seeking reimbursement from SAMI for those payments. Sometime during this period, Mrs. Eby began submitting claims to SAMI for handling fees. Despite the

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[3] Citation to the official transcript of the proceedings before the ALJ will be identified as "TR [Volume Number]/[Page]."

fact that BSN had advised Mrs. Eby of the appropriate procedures to be used in submitting such claims, Mrs. Eby claimed handling fees for services which were not reimbursable under the State Plan (i.e., urine cultures, urinalysis, pap smears and vaginal cultures when there was an office visit). Claims for these handling fees were consequently denied by BSN. TR 1/40-41, 90-91.

During the third period, August 13, 1981 through April 11, 1983, the period at issue in this case, the Respondent stopped reimbursing outside laboratories and instead, let the laboratory bill the SAMI program directly. TR I/61, TR III/544. The claims submitted during this period appeared in many respects to be identical to the claims submitted by Mrs. Eby during that period when the Respondent had been paying the outside laboratories. However, the claims did differ in one respect, namely that the claims submitted during this period did not explicitly request reimbursement for a specified amount certain, while the claims submitted during the prior period did. The record contains evidence that notwithstanding that difference the claims submitted during this period conveyed the impression to SAMI that the Respondent was seeking reimbursement for laboratory fees which he had paid on behalf of the program, when in fact no such payments had been made.

In all the claims at issue here, Mrs. Eby listed the 1974 CRVS procedure codes for the tests themselves and identified an outside laboratory as the facility performing the tests. As a result of Mrs. Eby's practices during this period, BSN paid Respondent $9,204.38 for the costs of the tests, based on the erroneous belief that the outside lab was being reimbursed by Respondent.

C.

In the course of discharging its contractual obligations, BSN discovered that Respondent was submitting claims for laboratory services that were in fact performed by outside laboratories and billed by those laboratories directly to SAMI. In October 1982, BSN referred the matter to NDHR which then commenced an investigation into Respondent's billing practices. TR I/126.

NDHR did not communicate with Respondent until May 2, 1983, when it requested that Respondent make available to its investigators certain medical and billing records. TR I/131. Commencing on July 8, 1983, NDHR investigators conducted a series of site visits to Respondent's office. During the course of those visits the investigators reviewed records and interviewed members of Respondent's staff, including Mrs. Eby, Respondent's bookkeeper.

As a result of its investigation, NDHR recommended that the State exclude Respondent from participation in the Medicaid program and referred the matter to the Inspector General of DHHS for further action.

The Inspector General instituted an investigation of the Respondent and as a result of that investigation determined that Respondent had caused to be filed 420 claims which included 1244 line items for services which had not been provided as claimed. The Inspector General advised Respondent that each of the line items or services represented charges to the Medicaid or Medicare Programs for laboratory services which were either never performed by Respondent as claimed or had been separately billed by the particular laboratory performing the service. On August 2, 1985, Respondent was formally notified by the Inspector General of his intent to impose civil money penalties and assessments against him in the amount of $250,000 (penalties of $232,000 and assessments of $18,000), and to suspend him from participating in the Medicaid and Medicare programs for a period of ten years.

Respondent, following receipt of the Inspector General's Notice of Determination, requested a hearing before an ALJ, under 45 CFR § 101.109(b)(2). A prehearing conference was held in Reno, Nevada on October 25, 1985, and a full evidentiary hearing was conducted in Law Vegas, Nevada commencing January 13, 1986, and ending on January 16, 1986. At the hearing, evidence was presented by the Inspector General that Respondent had authorized his bookkeeper, Mrs. Kathleen Eby, to not only compile the billings in general, but also to sign them on his behalf. No evidence was presented which would

indicate that the Respondent knew of Mrs. Eby's improper billing practices; no evidence was presented which would indicate that Respondent and Mrs. Eby had conspired to submit improper claims; and no evidence was presented which would indicate that Respondent had intentionally developed office procedures designed to insulate himself from the improper practices of his staff.

On July 11, 1986, the ALJ issued his Decision and Order. In that Decision, the ALJ applied the "should have known" standard and determined, based on that standard, that Respondent was liable under the CMPL for causing to be filed 418 false claims that contained at least 1244 incorrect or false line items. The ALJ further found that there was insufficient evidence to establish fraud or conspiracy on the part of the Respondent. Respondent, nevertheless, was found liable for the actions of Mrs. Eby, since he "should have known" that his billing clerk was submitting false claims for a period of over two years. See Decision and Order, p. 36. The ALJ concluded:

> [t]hat the Respondent was motivated during the time in issue by his desire to practice medicine as he saw it and not to be bothered by paperwork, clerical duties or to be involved with matters that he considered to be beneath him . . . He intentionally chose to ignore those important rules and regulations because he is not fond of governmental intrusion or regulation (with regard to the practice of medicine) and does not like the burdens placed upon him by Medicare and Medicaid. Decision and Order, pp. 25-26.

Again at page 27 of his Decision and Order the ALJ noted:

> I found Respondent did have a reckless disregard for the Medicaid program's ground rule and regulations *and chose to leave the important function of billing to Mrs. Eby without supervision.* (emphasis supplied)

Following the issuance of the ALJ's Decision and Order, Respondent, pursuant to 45 CFR § 101.125, requested administrative review by the Secretary. The discretionary review authority set forth in 45 CFR § 101.125 has been delegated to the Under Secretary and redelegated to the Deputy Under Secretary. By letter of December 8, 1986, I granted Respondent's request for review.

II.

Liability under the CMPL attaches only where it has been established that the respondent "knows or has reason to know" that medical services were not provided as claimed. In the case *sub judice* the ALJ consistently used the incorrect standard in judging the Respondent's liability. Rather than ascertaining whether the Respondent had "reason to know" that the claims were improper, as required by the statute, the ALJ applied a different, and clearly erroneous standard, namely: Whether the Respondent *should have known* that the claims were improper. The Inspector General concedes that the ALJ used the incorrect standard in judging the propriety of the Respondent's conduct. However, he urges that that error of law was harmless and that the Decision of ALJ should be affirmed for three independent reasons. First, the Inspector General argues that the CMPL imposes vicarious liability on an employer for the conduct of its employees acting within the course and scope of their employment. Second, the evidence adduced at the hearing is sufficient to support a finding that the Respondent actually "knew" that the claims submitted to the intermediary were improper. And third, the evidence is sufficient to support a finding that the Respondent had "reason to know" that the claims were improper.

A.

The common law doctrine of vicarious (or imputed) liability holds that under certain well-delineated circumstances an individual is to be held responsible for the acts of others even though that individual behaved in a totally acceptable manner. The doctrine is most commonly encountered under the

rubric of respondeat superior, where the actions of an employee are imputed for purposes of tort liability to the employer. *See Ira S. Bushey & Sons, Inc. v. United States*, 398 F.2d 167 (2d Cir. 1968).

The basic doctrine enjoys unquestioned acceptance in all common law jurisdictions. An unbroken line of decisions has held an employer responsible in tort for the employee's negligence even where the employer had expressly, indeed emphatically, forbade the very conduct that constituted the negligence of the employee. *See Limpus v. London General Omnibus Co.*, 1 H. & C. 526, 158 Eng. Rep. 993 (Ex. 1862). Although the doctrine appears to foster numerous distinct, but often competing, societal goals,[4] two have stood out: loss spreading and profit. While the concept of loss spreading is not relevant to our inquiry, the notion of profit deserves attention. That rationale holds that just as the employer gets the benefits from the gains for his worker's activities, so too, should he be required to bear the losses from those activities. The profit rationale has been used by courts to extend the doctrine of respondeat superior to cover instances involving intentional torts and indeed, even criminal breaches. In *New York Central & H. R. R. Co. v. United States*, 212 U.S. 481, 493 (1909), for instance, the Court noted that

> liability is not imputed because the principal actually participates in the malice or fraud, but because the act is done for the benefit of the principal, while the agent is acting with the scope of his employment in the business of the principal . . .

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[4] One academic writer identified nine traditional rationales for vicarious liability: control; profit; revenge; carefulness and choice; identification; evidence; indulgence; danger; and satisfaction. He then concluded that none of the nine could fully account for the doctrine: "If one turns to the opinions of judge or books upon the subject seeking a justification, disappointment is almost inevitable. True it is that many reason have been given, but none of them are [sic] satisfying." Y.B. Smith, *Frolic and Detour*, 23 Colum. L. Rev. 444, 454 (1923).

More recently, the Court in upholding the power of Congress to "personify a company" for purposes of criminal liability, spelled out that it was "through the doctrine of respondeat superior [that] corporations and other . . . impersonal entities can be guilty of 'knowing' or 'willful' violations of regulatory statutes . . . " *United States v. A. & P. Trucking Co.*, 358 U.S. 121, 125, (1958). The Court's rationale was couched in familiar phraseology borrowed from civil tort law, namely: "The treasury of the business may not with impunity obtain the fruits of violations which are committed knowingly by agents of the entity in the scope of their employment." *United States v. A. & P. Trucking Co.*, 358 U.S. at 126.

In light of the doctrine's universal acceptance, it is somewhat surprising to note that there is substantial disagreement over whether the doctrine should extend to include punitive damages.[5] Although a majority of courts have held that vicarious liability extends to punitive damages, even in the absence of approval or ratification by the principal, a substantial minority have held to the contrary. In fact there appears to be a recent trend in favor of the so-called minority position.[6] The *Restatement (Second) of Torts* § 909 (1979), which is intended to be a barometer of judicial behavior, limits a principal's responsibility for punitive damages to those cases in which high echelon officials of the principal are actually involved in

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[5] It should be noted that from a theoretical perspective the issue of whether the doctrine of respondeat superior supports the imposition of liability in the event of an intentional act is distinct from the issue of whether the doctrine supports the imposition of punitive damages. An employer may be liable for compensatory damages caused by an intentional act of his employee and yet, at the same time, escape liability with respect to a punitive damage claim.

[6] In *Kline v. Multi-Media Cablevision, Inc*, 233 Kan. 988, 666 P.2d 711 (1983), the court specifically adopted the minority position as set forth in the *Restatement (Second) of Torts*. Similarly, the Wyoming Supreme Court in *Campen v. Stone*, 635 P.2d 1121 (1981), specifically rejected the majority position and adhered to the dictates of the *Restatement (Second) of Torts*.

the tortious conduct.[7] The *Restatement* appears to have adopted the holding of the Supreme Court in *Lake Shore & M.S.R. Co. v. Prentice*, 147 U.S. 101 (1893), where the issue was whether in the absence of statutory authority a corporation could be liable in punitive damages for the tort of its employee. The Court, reasoning largely from general principles of respondeat superior, held that such vicarious liability could exist only when the employer had authorized and ratified the tort. Notwithstanding the recent expansion of the punitive damage doctrine, though, the Supreme Court has not revisited the issue of whether the common law permits the vicarious imposition of punitive damages.[8]

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[7] The *Restatement (Second) of Torts* § 909 provides as follows:

> Punitive damages can properly be awarded against a master or other principal because of an act by an agent if, but only if,
>
> (a) the principal or a managerial agent authorized the doing and the manner of the act, or
>
> (b) the agent was unfit and the principal or a managerial agent was reckless in employing or retaining him, or
>
> (c) the agent was employed in a managerial capacity and was acting in the scope of employment, or
>
> (d) the principal or a managerial agent of the principal ratified or approved the act.

[8] The Supreme Court's failure to re-address the issue of whether vicarious liability should encompass punitive damages may reflect little more than the Court's unwillingness to enter an area that has been traditionally governed by state law. Common law remedies, after all, tend to be a function of state rather than federal law. However, it is noteworthy that the Court has on a number of occasions declined to review this issue even when it has arisen in the context of a federal statute. In *Bateman Eichler, Hill Richards, Inc. v. Berner*, 472 U.S. 299, 314 n.25 (1985), for example, the Court declined to decide whether the *in pari delicto* defense would extend to bar recovery against a stock brokerage firm whose only role has been that of a "controlling

(Footnote Continued)

There is little question that if the government in this case were pursuing a common law remedy against the Respondent in a jurisdiction following the majority rule, the evidence would be more than adequate to support an award of punitive damages. The record amply reflects the fact that Mrs. Eby, the Respondent's bookkeeper, acted recklessly at best and with a "touch of larceny", at worst. However, the case *sub judice* does not involve a common law tort action. Nor does it involve a generic civil penalty statute, which is broad enough to encompass common law remedies. Instead, here the government relies solely on a highly specialized, carefully crafted statute aimed at deterring fraud and abuse in the Medicare and Medicaid programs. The statute specifies the types of penalties that are appropriate and the circumstances under which they may be imposed. Since the CMPL is a creature of statute, the starting point for determining whether vicarious liability is appropriate is the words of the statute itself. *Department of Transportation v. Paralyzed Veterans of America*, ____ U.S. ____, 106 S.Ct. 2705, 2710 (1986); *Reiter v. Sonotone Corp.*, 442 U.S. 330, 337 (1979); *Blue*

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person", as defined in 15 U.S.C. § 78t(a), of the defrauding employee and whose liability is therefore vicarious. *See, Mitchell v. General Motors*, 725 F.2d 385 (9th Cir. 1984), *cert. denied, sub nom. General Motors v. Mitchell*, 53 U.S.L.W. 3895 (1985) (punitive damages imposed on employer under the Civil Rights Act of 1866 for actions of employee). However, in *City of Newport v. Fact Concerts, Inc.*, 453 U.S. 247 (1981), the Court held that punitive damages could not be awarded against a municipality under 42 U.S.C. § 1983. Although one could argue that *Newport* implies that vicarious liability for punitive damages is suspect, the Court's opinion rested on a narrower ground, namely that the Civil Rights Act of 1871 did not contemplate imposing punitive damages on municipalities under any set of circumstances. In *General Bldg. Contractors Ass'n v. Pennsylvania*, 458 U.S. 375 (1982), the Court was asked to address the issue of whether the doctrine of respondeat superior applied to actions arising under 42 U.S.C. § 1981. The Court, in ruling that the facts of the case were insufficient to warrant application of the doctrine, found it unnecessary to address the basic issue. Most recently, in *Meritor Savings Bank, FSB v. Vinson*, ____ U.S. ____, 106 S.Ct. 2399, 2408 (1986), the Court specifically "decline[d] the parties' invitation to issue a definitive rule on employer liability [under Title VII of the Civil Rights Act of 1964] . . . " However, the Court did note that employers are not "always automatically liable for sexual harassment by their supervisors." *Id.*

Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 756 (1975) (Powell, J., concurring). The CMPL provides in pertinent part as follows:

> Any person . . . that –
>
> (1) presents or causes to be presented to an officer, employee, or agent of the United States, . . . a claim . . . that the Secretary determines is for a medical or other item or service
>
> > (A) that the person knows or has reason to know was not provided as claimed . .
>
> (2) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $2,000 for each item or service . . .

Here, unlike other civil money penalty statutes, the CMPL explicitly recognizes the distinction between the actions of the principal and those of the agent. Specifically, by juxtaposing the terms "presents" or "or causes to be presented" the statute contemplates situations, such as the one at bar, where the individual who actually submits the improper claim is not the principal, but an employee who merely submitted the claim in the course of the employment. However, in such instances, the statute expressly limits the liability of the principal to only those situations where the principal either knows or has reason to know that the claims were improper. In short, the clear of language CMPL expressly precludes the application of the doctrine of vicarious liability, and instead requires the Inspector General to establish *actual* malfeasance or misfeasance on the part of the principal.

Common law principles notwithstanding, the courts have been understandably reluctant to impose vicarious liability where the language of a civil penalty statute indicates to the contrary. For example, in *United States v. Turner*, 601 F.Supp. 757 (E.D.WI. 1985), a case involving a statute semantically

similar to the CMPL, the government, in seeking to impose liability on one partner on account of the activities of the other partners, argued that vicarious liability would be appropriate because the statute in question closely parallels the law of torts.[9] The court, in refusing to impose vicarious liability under the abusive tax shelter provisions of TEFRA, looked to the wording of the statute and held that "only the person who actually made or furnished the fraudulent statement is liable. . . " *Id.* at 759. The holding in *Turner* is particularly instructive, because there, unlike here, the so-called innocent partner actually knew what his partners were doing and was present at meetings where they had furnished fraudulent information.[10]

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[9] *Turner* involved certain tax shelter provisions of TEFRA which imposed criminal and civil liability on any person who in the course of promoting an abusive tax shelter:

> (2) makes or furnishes (in connection with such organization or sale) –
>
> > (A) a statement with respect to the allowability of any deduction or credit, the excludability of any income, or the securing of any other tax benefit by reason of holding an interest in the entity or participating in the plan or arrangement which the person *knows or has reason to know* is false or fraudulent as to any material matter, or
> >
> > (B) a gross valuation overstatement as to any material matter . . .

26 U.S.C § 6700(a)(2) [emphasis supplied].

[10] *See Larimore v. Comtroller of the Currency*, 789 F.2d 1244 (7th Cir. 1986) (*en banc*) (holding that the federal banking laws did not authorize the Comptroller to administratively impose civil penalties on a bank director who did not know or have reason to know that the bank's lending limits had been exceeded); *Amoco Oil Co. v. Environmental Protection Agency*, 543 F.2d 270 (D.C.Cir. 1976) (invalidating, as beyond the scope of the enabling legislation, agency regulations which imposed vicarious liability on refiners on account of the actions of their retail dealers); *Rochez Brothers, Inc. v. Rhades*, 527 F.2d 880 (3d Cir. 1975), *cert. denied*, 425 U.S. 993 (1976) (holding that the provisions of Securities Exchange Act do not authorize wholesale incorporation of the doctrine of respondent superior); *United States v. Ottati & Goss, Inc.*, 630 F.Supp. 1361 (D.N.H. 1985); *but see Sharp v. Coopers & Lybrand*, 649 F.2d 175 (3d Cir. 198') (recognizing that in certain circumstances imposition of vicarious liability would be consistent with the securities laws).

The Inspector General in urging the incorporation of the doctrine of vicarious liability sidesteps the language of CMPL and instead focuses on the use of that doctrine in the common law and in other civil penalty schemes.[11] Clearly, analogizing to common law principles is only appropriate where the statute under scrutiny is either silent or ambiguous. Here, the statute is neither silent nor ambigious. The CMPL on its face requires the government to establish affirmatively that the principal, i.e., the person under whose control the agent acted, actually knows or has reason to know that the actions of the agent were improper. Thus, the CMPL expressly precludes the normal application of the doctrine of vicarious liability. Consequently, the Inspector General's reliance on common law principles of imputed liability is misplaced.

The Inspector General also argues that courts have adopted the doctrine of vicarious liability in the context of other statutory schemes. Specifically, the Inspector General notes that in *United States v. Sweet Briar, Inc.*, 92 F.Supp. 777 (W.D.S.C. 950) the court imposed liability on an employer for the acts of its employee. In *Sweet Briar* the defendant corporation was charged under the Walsh-Healey Public Contracts Act with having hired female employees who were under the age of sixteen (16). However, in *Sweet Briar* the statute and the implementing

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[11] Courts have consistently imposed vicarious liability in the context of a civil money penalty statute, where the language of that statute is broad enough to accommodate the use of the doctrine. Thus, in *West v. Costen*, 558 F.Supp. 564 (W.D. Va. 1983), the court held that under the Fair Debt Collection Practices Act, a collection agency was responsible for the acts of its debt collectors. Also, in *Bituminous Coal Operators' Assn., Inc.*, 547 F.2d 240 (4th Cir. 1977), the court ruled that the Federal Coal Mine Health and Safety Act of 1969 authorized the imposition of penalties on coal mine owners for the wrongful acts of their independent contractors. Similarly, in *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557 (6th Cir. 1985), the court affirmed civil money penalties against the president of the defendant corporation because, in the opinion of the court, the term "manufacturer", as used in the Radiation Control for Health and Safety Act of 1968, was sufficiently broad to include a major shareholder or corporate president. *See United States v. Park*, 421 U.S. 658 (1975) (holding that a corporate officer could be held criminally liable for violations of the Food, Drug & Cosmetic Act).

regulations specifically imposed liability on the principal for the acts of its agents in knowingly hiring individuals who were under age. In short, under the terms of Walsh-Healey the knowledge of the agent was expressly imputed to the principal. Here, in sharp contrast, the CMPL requires as a condition of imposing liability on the principal that the principal itself possess the requisite knowledge. If nothing else, *Sweet Briar* evidences the fact that Congress knows full well how to craft language that would impose vicarious liability, but chose instead to do otherwise. The short answer then to any contention that the CMPL authorizes vicarious liability "is that Congress did not write the statute that way." *United States v. Naftalin*, 441 U.S. 768, 773 (1979). Reliance on other statutory schemes is therefore misplaced.

In addition, the Inspector General notes that certain courts in applying the False Claims Act, a law closely analogous to the CMPL, have implied that vicarious liability may in fact be appropriate. Specifically, in *Miller v. United States*, 550 F.2d 17 (Ct.Cl. 1977), the court held a contractor liable under the False Claims Act for ineptitude evidenced by among other things, slipshod supervision of his workmen. However, in *Miller* the contractor steadfastly maintained that he always checked his men's work personally, that he actually knew that the quantities of materials billed by his workmen were only estimates of what had actually been used, and further, that he made no effort to correct these estimates. Thus, in *Miller* the court was not required to address, and in fact, did not address the issue of vicarious liability. Liability there rested on unrefuted evidence that the contractor had actual knowledge that his billings were in fact erroneous. Here, in sharp contrast, there is no evidence that the Respondent had such knowledge.

In conclusion, I have not been apprised of any case or legislative gloss that would in anyway undercut the plain meaning of the CMPL.

B.

The Inspector General maintains that the Decision below ought to be affirmed because the evidence adduced at the

hearing demonstrates that the Respondent actually "knew" that improper billings were being submitted by his billing clerk. At the outset it should be noted that there is no evidence, credible or otherwise, to support the proposition that the Respondent had actual knowledge of the improper billings at issue. The Inspector General tacitly concedes this point. Moreover, the ALJ found the record insufficient to support a claim of actual knowledge. The ALJ did find, however, that the Respondent acted with reckless disregard in failing to properly supervise the activities of his billing clerk, and as a result thereof, the Respondent should have known that improper billings were being submitted on his behalf. In light of these findings of fact, the Inspector General forcefully argues that the word "knows," as used in the CMPL, encompasses knowledge that the Respondent would have had had he acted reasonably. In short, the propriety of the ALJ's legal analysis hinges on the meaning of the word "knows."

The word "knows" though is a classic "weasel" word, with a slippery meaning that is highly dependent upon the context in which it is used. In certain settings courts have held for instance, that whether an actor has knowledge is to be judged subjectively, by examining what knowledge the actor actually possessed. *See United States v. Harvey,* No. 86-5025 (4th Cir. 3/6/87) (holding that under the Comprehensive Forfeiture Act, an attorney's knowledge of the source of his fees must be judged against a subjective standard). In other settings, though, courts have held that the existence of knowledge is to be judged objectively and in terms of what the actor should have known, as opposed to what he actually knows. While context appears to account for much of the term's definitional variance, traditional notions of pragmatics and presupposition, however, cannot fully explain its extreme fluidity. Much of this variance undoubtedly derives from the uncertainty and ambiguity that have surrounded other referents of scienter (e.g., "malice", "wantonness", "reckless disregard", to name a few). It is not surprising then that courts, as illustrated below, have had difficulty agreeing on a common meaning even within the context of the same statute.

The judiciary's experience with the term "knowing" as it appears in the False Claims Act is particularly instructive for a variety reasons. First, it emphasizes the degree to which courts have differed on the meaning of the word even within a single statute. Second, since the CMPL parallels in certain respects the False Claims Act, cases interpreting that act may be helpful in fleshing out the contours of the CMPL. And third, the Inspector General has relied heavily on court decisions concerning the False Claims Act in interpreting the CMPL. The False Claims Act provides in pertinent part as follows:

> Any person . . . [1] who shall make or cause to be made, or present or cause to be presented for payment . . . any claim upon or against the Government of the United States . . . knowing such claim to be false, fictitious, or fraudulent . . . shall forfeit and pay to the United States the sum of $2,000, and, in addition, double the amount of damages which the United State may have sustained . . .

The Inspector General correctly observes that under the False Claims Act there is a substantial body of case law equating "reckless disregard" with actual knowledge. In *United States v. Cooperative Grain and Supply Co.*, 476 F.2d 47 (8th Cir. 1973), the court held that extreme carelessness of the defendants in not ascertaining whether purchased grain was eligible for commodity price support was "knowing" within the False Claims Act. In so holding the court reasoned that since the False Claims Act is civil in nature,

> the definition of "knowing" should be the definition as applied in the civil action of misrepresentation. Prosser classifies misrepresentation into "the three familiar tort classifications of intent, negligence, and strict responsibility." . . . Since we have decided that a false claim, not only a fraudulent claim, is actionable under the Act, a negligent misrepresentation can constitute the necessary "knowledge".

Cooperative Grain and Supply Co., 476 F.2d at 60.

The United States Court of Claims in *Miller v. United States*, 550 F.2d 17, 23 (Ct.Cl. 1977) echoed the sentiments of the Eight Circuit in *Cooperative Grain and Supply Co.* in holding that negligent misrepresentation is sufficient to satisfy the "knowledge" requirement of the False Claims Act. However, as the Inspector General candidly notes, other courts have read the False Claims Act far less liberally than either the Eight Circuit or the Court of Claims. For instance, the Sixth and Seventh Circuits have held that proof of actual knowledge is required in order to sustain liability under the False Claims Act. See *United States v. Hughes*, 585 F.2d 284 (7th Cir. 1978); *United States v. Ekelman & Assoc.*, 532 F.2d 545 (6th Cir. 1976). The rule in the Fifth and Ninth Circuits is even stricter, requiring proof that the defendant not only had actual knowledge but also a specific intent to defraud the government. See *United States v. Thomas*, 709 F.2d 968 (5th Cir. 1983); *United States v. Mead*, 426 F.2d 118 (9th Cir. 1970).

Had I been asked to judge the Respondent's conduct in light of the False Claims Act and had I been writing on a clean slate, I would have been inclined to follow the soundly reasoned opinion of the court in *Cooperative Grain and Supply Co.* and to have adopted the well articulated position of the Inspector General. However, the Respondent's conduct must be judged in light of the language of the CMPL and the language of that statute differs from the language of the False Claims Act in certain critical respects that cannot ignored. Liability under the False Claims Act hinges on a finding that the defendant "knowingly" submitted false claims. In contrast, liability under the CMPL hinges on a finding that the respondent "knows" or had "reason to know" that the claims were improper. Had the Congress not added the phrase "has reason to know" then one would be justified in adopting the interpretation given the word "knowing" by the court in *Cooperative Grain and Supply Co.* There the court in essence held that a person has actual knowledge of a false claim if that person *should have known* that the claim was false. The phrase "has reason to know" though severely restricts the meaning of the word "knows," and effectively precludes one from adopting the broader interpretation urged by the Inspector General.

The phrase "has reason to know" has a highly specialized and well established meaning. The term "reason to know" is defined in the *Restatement (Second) or Torts* § 12 (1965) and *Restatement (Second) of Agency* § 9 (1957) to mean that an actor actually has information from which a person of reasonable intelligence would infer that the fact in question exists. The term "reason to know" differs in one important respect from the closely related term "should know." The latter term implies that the actor is under a duty to ascertain all pertinent information. The former term, i.e., "reason to know", implies that the actor is under no duty to ascertain that information. *Burgess v. Montgomery Ward and Company,* 498 F.2d 495, 498 (10th Cir. 1959) (holding that the "phrase 'reason to known' as used in the Restatement does not imply any duty to ascertain an unknown fact"). The duty to investigate further arises only after the actor actually learns of the pertinent information. As here, where the Congress borrows

> terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word . . . In such case, absence of contrary direction may be taken as satisfaction with the widely accepted definitions, not as a departure from them.

Morrissette v. United States, 342 U.S. 246, 264 (1952). Consequently, I must assume that when the Congress engrafted the phrase "reason to know" onto the CMPL it did so with a clear understanding of its meaning and effect. If Congress had intended the word "knows" to encompass the concept of "should know" then there would have been no need to add the phase "reason to know," since the former subsumes the latter. The phrase "reason to know" would then have been purely superfluous. It is by now axiomatic that a statute must be read to give effect to every word, clause and sentence of that statute. *See United States v. Menasche,* 348 U.S. 528, 538-39 (1955); *Montclair v. Ramsdell,* 107 U.S. 147, 152 (1882). It would be ill advised for any court or administrative body to blithely

ignore as superfluous the words of any statute,[12] especially, where as here, the statute imposes significant civil penalties. *See Brennan v. Occupational Safety & Health Rev. Com'n.*, 511 F.2d 1139, 1144 (9th Cir. 1975) (holding that it would be improper to read-out of a civil penalty statute the concept of "knowledge"); *Willamette Subscription Television v. Cawood*, 580 F.Supp. 1164 (D.Or. 1984). One must therefore assume in the absence of legislative history to the contrary that the Congress intended to give meaning to the phrase "reason to know" when it used that phrase in the CMPL. As noted above, though, the phrase only has meaning if one interprets the word "knows" to refer only to actual knowledge and not to knowledge that the actor should have had had he acted reasonably. This reading is entirely in accord with cases interpreting other civil penalty statutes. For instance, in *United States v. Four Million Two Hundred Fifty-Five Thousand Dollars in U.S. Currency*, 762 F.2d 895, 905 (11th Cir. 1985), the government urged that the forfeiture provisions of the Controlled Substances Act, 21 U.S.C. § 881(a)(6) provides that "no property shall be forfeited . . . to the extent of the interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without the *knowledge or consent of the owner.*" [emphasis supplied]. The Court, in rejecting the government's position, held that the propriety of the forfeiture turns on claimant's actual knowledge not constructive knowledge. *See United States v. Premises Known As 2639 Meetinghouse*, 633 F.Supp. 979, 992-93 (E.D.Pa. 1986).

In conclusion, I find that the word "knows" as used in the CMPL refers only to actual knowledge and not to knowledge that the actor should have had. I further find, as did the ALJ below, that the record in this case is uniquely devoid of any evidence which would indicate that the Respondent had actual knowledge that the claims at issue were in fact improper.

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[12] In *Tabor v. Ulloa*, 323 F.2d 823, 824 (9th Cir. 1963), the court noted that a "legislature is presumed to have used no superfluous words" in a statute. *See International Society for Krishna Consciousness v. Lee*, 105 FRD 435, 449 (S.D.N.Y. 1984).

C.

The Parties have devoted considerable attention to an analysis of whether liability may be imposed under the CMPL for conduct which amounts to mere negligence. The Respondent has argued that liability can only be imposed if a person acted intentionally or, at the least, recklessly. The Respondent further argues that his conduct was neither intentional nor reckless. The Inspector General maintains that liability may be imposed even in the absence of reckless conduct, that mere negligence will suffice and further that the Respondent acted negligently. Specifically, the Inspector General maintains that the evidence adduced at the hearing demonstrates that the Respondent had "reason to know" that the claims submitted on his behalf were erroneous.

At the outset it must be reiterated that the form of any action under the CMPL must be governed by the language of the statute and not by common law principles. Civil penalty statutes vary widely in terms of scope and penalty. Some statutes impose significant penalties on a strict liability basis; other statutes impose modest penalties, but only upon a showing of malice. The notion championed by the Respondent, that liability can only attach upon a showing of fraud or other conduct bordering on fraud, is contrary to both the plain meaning of the CMPL and its legislative history.

As noted above, where the resolution of an issue turns on the meaning of a statute, courts look first to the language of the statute and then, if necessary, to its legislative history. *Blum v. Stenson*, ____ U.S. ____, 104 S.Ct. 1541, 1548 (1984). The language of the CMPL is clear on its face. Liability attaches upon a showing that a respondent either "knows or has reason to know [that a medical item or service] was not provided as claimed." 42 U.S.C. § 1320-7a(a)(1)(A) (1982). The statute does not require a showing of fraud; it does not require a showing of evil intent; and it does not even require a showing of actual knowledge. The wording of the statute is unambiguous: liability may be imposed if a respondent "has reason to know" that

services were not provided as claimed. The Constitution demands no more than that and the statute requires no more. *See Mayers v. U.S. Dept. of Health and Human Services*, No. 85-3803 (11th Cir. Dec. 22, 1986) (holding that the Congress can impose civil penalties and even criminal sanctions without proof of *mens rea*). Thus, Respondent's argument that certain unidentified common law principles require a heightened showing of culpability is entirely without merit.

The legislative history surrounding the adoption of the CMPL, although meager, in no way undermines the plain meaning of the statute. On August 31, 1981, Congress passed the CMPL, as an alternative procedure to existing federal enforcement mechanisms. Congress found that the existing mechanisms, most notably the criminal fraud provisions of medicare and medicaid, were inadequate to combat the increasing incidence of Medicare and Medicaid fraud and abuse. *Griffon v. United States Dept. of Health and Human Services*, 802 F.2d 146, 148-49 (5th Cir. 1986). Congress found that due to the large volume of such cases, the Department of Justice was only able to institute criminal proceedings where the amount of money involved was substantial or the conduct was particulalry egregious. As a result, "criminal penalties have proved an ineffective deterrent to fraudulent practices under medicare and medicaid." H.R.Rep. No. 97-158, 97 Cong., 1st Sess., vol. III, 327 (1981). The CMPL thus was intended to provide an alternative to criminal proceedings so as to increase the effectiveness of enforcement by providing the Secretary with a non-criminal administrative mechanism for deterring fraud and abuse. While, I am not unmindful of the fact that the legislative history consistently speaks in terms of "fraud", there is nothing in that history that would in any indicate an intent on the part the Congress to restrict the scope of the CMPL to cases involving only actual fraud. Indeed, as Respondent acknowledges, the legislative history does in fact make reference to the "reason to know" standard--a standard that is inextricably linked to negligence. Moreover, the fact that the statute imposed civil, as opposed to criminal, sanctions indicates an intent on the part of Congress to expand the coverage of the then existing deterrent mechanisms. As the court in *Griffon* aptly noted: "In addition, the CMPL creates

new substantive liability if a claim-filer 'has reason to know' that her claims are false . . . " *Griffon v. United States Department of Health and Human Services*, 802 F.2d at 150. The "reason to know" standard is unique; it creates what can best be described as a negligence based-tort with a "springing duty."

The linchpin of modern negligence is the existence of a duty owed by the defendant to the plaintiff. *See* Green, *The Duty Problem in Negligence Cases*, 28 Colum. L. Rev. 1014 (1928). "Proof of negligence in the air, so to speak, will not do." Pollock, *Torts* 468 (13th ed. 1929). Thus, negligence is not actionable unless it involves the invasion of a legally protected interest. *Palsgraf v. Long Island R.R.*, 248 N.Y. 339, 162 N.E. 99 (1928). The "reason to know" standard which has been engrafted onto the CMPL represents an acknowledgement on the part of the Congress that a duty does not automatically exist to ferret out errors made by others. The duty, however, springs into existence once the actor has sufficient information to place a reasonable man under similar circumstances on notice that improper claims are in fact being filed. *Restatement (Second) of Torts* § 12. Once the duty attaches, the Respondent is liable for what he "should have known" had he investigated further. The concept of a springing duty is most commonly encountered in cases involving the liability of landowners for injuries sustained by those who enter the land as licensees. At common law, a landowner owes an affirmative duty of care to business invitees. Such invitees are entitled to enjoy the premises in a reasonably safe condition. In contrast, the landowner owes no such duty either to licensees, e.g., social guests, or to trespassers. In the case of licensees, the possessor is only liable if, among other things, the possessor knows or has reason to know of the dangerous condition that causes the harm and then fails to warn the licensee of that danger. *Restatement (Second) of Torts* § 342. In such cases, the duty to warn only springs into existence if the possessor is actually aware of information that would have put a reasonable man on notice of the danger or potential danger. The cases cited by the Inspector General in his Brief of February 6, 1987, aptly illustrate that point. In *Madison v. Deseret*

Livestock Co., 574 F.2d 1027 (10th Cir. 1978), the court, in applying Utah law, reversed a district court order granting summary judgment, because there were genuine issues of fact as to whether the defendant had reason to know of the hazardous condition. The Court of Appeals noted, for instance, that the hazard was visible from the road, that it existed for a few days and that defendant's ranch foreman acknowledged driving past the hazard on numerous occasions. In sum, a reasonable jury could have concluded that the foreman either knew or had reason to know of the hazard. Similarly, in *Christians v. Homestake Enterprises, Ltd.*, 25 Wis.2d 25, 303 N.W.2d 608 (1981), the trial court, using a "should know" standard, entered judgment in favor of the plaintiff-trespasser. The Wisconsin Supreme Court, after recounting the difference between the "should know" standard and the "reason to known" standard, adopted the latter, reversed the trial court judgment in favor of the plaintiff, and held that as to trespassing children, "the possessor is under no duty to inspect, but if the possessor knows of facts from whcih a reasonable person would infer that the condition in question exists . . . the possessor is charged with knowledge of the condition." *Id.* at 621. The court went on to conclude that a reversal was necessary because it was impossible to discern whether the jury had based its decision upon a finding that the defendant knew, had "reason to know," or "should have known" of the hazard. In summary, the cases illustrate that there is a discernible difference between the two standards, that use of the improper standard warrants reversal, and further, that to support a finding that a defendant has "reason to know," there must be specific, concrete evidence to indicate that the defendant actually knew enough to put a reasonable man on notice that further inquiry was warranted.[13]

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[13] For example, suppose that A invites his friend B to dinner. A does not know that his private road has been dangerously undermined at a point where it runs along an embankment and that it is not observable to a person driving along the road. However, A *could* have discovered the danger had he paid attention to his road. While B is driving along the road it collapses, causing serious harm to B. A is *not* liable to B. *Restatement (Second) of Torts*

(Footnote Continued)

See Restatement (Second) of Torts §§ 339, 342. At issue, then, in this case is whether the record, when taken as a whole, contains such specific, concrete evidence.[14]

The Inspector General maintains that the evidence adduced at the hearing is sufficient to support a finding that the Respondent had "reason to know" that one of his employees was submitting claims for laboratory services that either were not performed at all or were performed by an independent laboratory. In support of that proposition, the Inspector General points to a series of independent events that would have placed a reasonable man on notice that something amiss was occurring. First, the ALJ found that in 1977 the Respondent was advised that he was operating an unlicensed laboratory, but he made no effort to investigate or otherwise correct the problem. Second, in 1978, the Respondent was informed by SAMI that he had been overutilizing certain procedures and billing incorrectly for comprehensive examinations and that these abuses would have to cease. And third, in July 1983, the Respondent was advised that pap smears are considered part of the standard vaginal examination and therefore, may not be billed separately.

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§ 342, comment d, illustration 3. Also, in *Samuels v. Empress Lineas Maritimas Argentinas*, 573 F.2d 884 (5th Cir. 1978), a case noted by the Inspector General, the court, in affirming a jury verdict for the plaintiff under the Longshoremen's and Harbor Workers' Compensation Act, held that the evidence was sufficient of support a finding of negligence under the "reason to know" standard. In *Samuels* the plaintiff sustained injuries after falling through a hole in the cargo hold of a ship. Among others things, the court noted that the area in question was insufficiently illuminated, that this had been conveyed to ship personnel, but nothing was done to correct the situation. Moreover, the court emphasized that ship personnel had actually inspected the area shortly before the accident. In short, there was circumstantial evidence that ship personnel either knew of the hole, as a result of the inspection, or in the alternative, because of the poor illumination had reason to inspect further.

[14] It is by now a well-settled rule "that an erroneous ruling which relates to the substantial rights of a party is ground for reversal unless it *affirmatively* appears from the whole record that it was not prejudicial." *McCandless v. United States*, 298 U.S. 342, 347-48 (1936) (emphasis in the original).

An examination of the exhibits and supporting testimony concerning each of these three events reveals that these incidents, either when viewed separately or together, are insufficient to demonstrate that the Respondent had "reason to know" that from August 1981 through April 1983 his billing clerk was submitting improper Medicaid claims.

Both ALJ and the Inspector General devoted substantial attention to the 1977 investigation of the Respondent's unlicensed laboratory. Whatever that incident may reveal about the Respondent's attitude in 1977 toward paper work and federal intrusion into the practice of medicine, one thing is clear: the incident is simply irrelevant with respect to Mrs. Eby's billing practices in the period August 1981 through April 11, 1983. The record reveals that Mr. Norman Siegel visited the Respondent's office and laboratory on September 21, 1977. During the course of that visit he copied a number of patient charts, examined the physical premises and had a conversation with the Respondent. During that conversation Respondent indicated that he "knew nothing about billing SAMI." I.G. Ex. 424. Following Mr. Siegel's site visit, a "Confidential Report of Preliminary Investigation" was completed on February 8, 1978. I.G. Ex. 425. That report focused on a number of areas including Respondent's surgical practice and laboratory billings. The report concluded that there were "clinical finding[s] that could constitute support for the performance of an anterior/posterior vaginal repair in conjunction with the hysterectomy and indication in the Operative Report that it, in fact, was performed were [sic] found in all instances." The report went on to note that medical necessity was found in all instances for the laboratory procedures billed to SAMI. However, the report did note certain deficiencies, including that in 57% of the sample examined, there was no documentation to support the fact that laboratory procedures which had been billed to SAMI were in fact performed. In addition, the report also found that the Respondent's laboratory was not certified, as required by State law. The report concluded by listing a variety of "suggested action alternatives," including initiating a full-scale fraud investigation, obtaining restitution of all monies paid on account of tests

performed at Respondent's laboratory, terminating Respondent's provider agreement and/or discontinuing payments to Respondent for laboratory procedures. Notwithstanding this rather impressive report, it is surprising to find that none of the suggested alternatives was pursued, that the contents of the report were never shared with Respondent and that he was never even informed of the deficiencies noted in the report. In short, the entire incident provides no evidence that the Respondent had "reason to know" that the laboratory billing practices of Mrs. Eby were amiss.

The second event alluded to by the Inspector General is even less probative than the laboratory incident noted above. Specifically, on May 26, 1978, Respondent was advised via certified mail that in one instance he had billed for six comprehensive re-examinations in a six month period. The letter went on to note that only rarely do patients require such an intense level of care and that future use of the comprehensive re-examination must be restricted. There is simply no relationship between this event, which occurred in 1978 and involved medical judgment about the level of care to be accorded a single patient, and Mrs. Eby's billing practices, which occurred three years later and involved ministerial laboratory billing procedures. Moreover, there is nothing in the record that would even indicate that the Respondent's extensive use of the comprehensive re-examination for the one patient was in fact improper. That patient, may have been the rare case referred to in the SAMI letter.

The final event pointed to by the Inspector General as indicating that the Respondent had "reason to know" that Mrs. Eby's billing practices were improper occurred in July 1983 when SAMI investigators signed a note on Respondent's stationery acknowledging that a physician could not charge separately for a Pap smear. Clearly, a "warning" provided a full three months after the improper billings had ceased and which related to a billing practice not even at issue in this case cannot as matter of a law form the basis for a "reason to know" finding. Indeed, if nothing else, this final event provides

circumstantial evidence that Respondent did not fully comprehend SAMI billing regulations and insisted upon an official note to confirm the correct procedure.

In summary, the events alluded to by the Inspector General do not support the contention that the Respondent had "reason to know" that Mrs. Eby was filing incorrect claims with the fiscal intermediary. This is not to say, that Respondent's conduct was either proper or above reproach. It is clear that the Respondent was careless in not more carefully supervising the billing activities of his staff. However, it is equally clear that such carelessness, as long as it does not affect the quality of care afforded Medicaid patients[15] and as long as the Respondent did not have reason to know of it, is not actionable under CMPL.

In situations such as this, where an appellate tribunal discerns that the factfinder "has failed to make a finding because of an erroneous view of the law, the usual rule is that there should be a remand for further proceedings to permit the [factfinder] to make the missing findings" *Pullman-Standard v. Swint*, 456 U.S. 273, 291 (1982). As the Court in *DeMarco v. United States*, 415 U.S. 449, 450 (1974) observed:

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[15] Where the actions of a provider adversely affect the quality of medical care the constraints imposed by the "reason to know" standard no longer pertain. As noted above, the "reason to know" standard assumes that there is no pre-existing duty on the part of the provider to ferret out information. However, a provider always owes a duty of due care to each of his patients. Consequently, prosecutions under the CMPL which implicate the quality of care do not require independent proof to cause the duty to spring into existence. The duty to provide quality care always exists. In this case, the ALJ found that the Respondent did in fact practice quality medicine and there was nothing in the record to indicate that his carelessness in supervising his billing clerk had any adverse effect on the quality of care that he afforded his patients. The urinalyses that were billed to SAMI by Mrs. Eby, but never performed, were, based on the medical evidence adduced at the hearing, largely redundant. The urine cultures and other tests that were performed would have detected any abnormalities.

> [F]actfinding is the basic responsibility of district courts, rather than appellate courts, and . . . the Court of Appeals should not have resolved this factual dispute which had not been considered by the District Court.

Accordingly, since the ALJ did not review the record in light of the "reason to know" standard, the preferred course is to remand this matter to the ALJ to provide him with an opportunity to consider the evidence in light of that standard. It should be noted that the remand is limited to a single issue, namely whether there is evidence to support a finding that the Respondent "had reason to know" that improper claims were being submitted on his behalf.

III.

The decision reached today is not intended to limit or otherwise thwart the superb enforcement efforts of the Inspector General, which are vital to the Medicare and Medicaid programs and which remain above reproach in all respects. The actions of the Inspector General are not at issue in this case; his investigation and prosecution were both thorough and fair. This case, however, was, and remains, highly unusual and my decision must be read accordingly. It is the only case to my knowledge in which an ALJ found no evidence of fraudulent intent, found no evidence of actual knowledge, found no evidence of conspiracy or complicity on the part of a respondent, and found no evidence that the Respondent had intentionally implemented office procedures designed to insulate himself from the improper practices of his staff. In short, this case tested the outer limits of the CMPL. Under normal circumstances, subtle legal distinctions are not infrequently ignored by courts with little risk to justice. In *Mayers v. U.S. Dept. of Health and Human Services*, No. 85-3803 (11th Cir. Dec. 22, 1986), for instance, the court confused the "should know" standard and the "reason to know" standard treating the two as if they were equivalent. *Mayers*, though, involved a mundane case of clear fraud under the CMPL and the court's "error," such as it was, had no affect on its holding. Here, given the unique facts of

this case, the subtle distinction between the two standards did have meaning, and the ALJ's failure to recognize that distinction by consistently using the incorrect legal standard, constituted prejudicial error mandating reversal. When venturing on the outer limits of a statute it is easy to misstep and ignore those subtle legal distinctions which under normal circumstances would have little import. As Roger Traynor noted: "To err is human, as a judge well knows, but to err is not always harmless." Traynor, *The Riddle of Harmless Error* 3 (1970).

Accordingly, for the reasons discussed above, the Decision of the ALJ is reversed, the Order vacated and the case is remanded to the ALJ for proceedings consistent with this Opinion and with the attached Order.

s/Robert L. Raclin

Robert L. Raclin
Deputy Under Secretary

APPENDIX E

Social Security Act, § 1128A, 42 U.S.C. § 1320a-7a (1983 & Supp. 1973).

§ 1320a-7a. Civil monetary penalties

(a) Improperly filed claims

Any person (including an organization, agency, or other entity) that—

(1) presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (h)(1) of this section), a claim (as defined in subsection (h)(2) of this section) that the Secretary determines is for a medical or other item or service—

(A) that the person knows or has reason to know was not provided as claimed, or

(B) payment for which may not be made under the program under which such claim was made, pursuant to a determination by the Secretary under section 1320a-7, 1320c-9(b), or 1395y(d) of this title, or pursuant to a determination by the Secretary under section 1395cc(b)(2) of this title with respect to which the secretary has initiated termination proceedings; or

(2) presents or causes to be presented to any person a request for payment which is in violation of the terms of (A) an assignment under section 1395u(b)(3)(B)(ii) of this title, or (B) an agreement with a State agency not to charge a person for an item or service in excess of the amount permitted to be charged, or (C) an agreement to be a participating physician or supplier under section 1395u(h)(1) of this title,

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $2,000 for each item or service. In addition, such a person shall be subject to an assessment of not more than twice the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim.

(b) Initiation of Proceedings; authorization by Attorney General, notice, etc.

(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty or assessment under subsection (a) of this section only as authorized by the Attorney General pursuant to procedures agreed upon by them.

(2) The Secretary shall not make a determination adverse to any person under subsection (a) of this section until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under subsection (a) or (b) which—

> (A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and
>
> (B) involves the same transaction as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established.

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense,

(C) striking pleadings, in whole or in part,

(D) staying the proceedings,

(E) dismissal of the action,

(F) entering a default judgment,

(G) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct, and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(c) Amount or scope of penalty or assessment

In determining the amount or scope of any penalty or assessment imposed pursuant to subsection (a) of this section, the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and

(3) such other matters as justice may require.

(d) Review by courts of appeals

Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the court the record in the proceeding as provided in section 2112 of Title 28. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the

jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of Title 28.

(e) Compromise of penalties and assessments; recovery; use of funds recovered

Civil money penalties and assessments imposed under this section may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim was presented, or where the claimant resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and disposed of as follows:

(1)(A) In the case of amounts recovered arising out of a claim under subchapter XIX of this chapter, there shall be paid to the State agency an amount equal to the State's share of the amount paid by the State agency for such claim.

(B) In the case of amounts recovered arising out of a claim under an allotment to a State under subchapter V of this chapter, there shall be paid to the State agency an amount equal to three-sevenths of the amount recovered.

(2) Such portion of the amounts recovered as is determined to have been paid out of the trust funds under sections 1395i and 1395t of this title shall be repaid to such trust funds.

(3) The remainder of the amounts recovered shall be deposited as miscellaneous receipts of the Treasury of the United States.

The amount of such penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be

deducted from any sum then or later owing by the United States or a State agency to the person against whom the penalty or assessment has been assessed.

(f) Finality of determination respecting penalty or assessment

A determination by the Secretary to impose a penalty or assessment under subsection (a) of this section shall be final upon the expiration of the sixty-day period referred to in subsection (d) of this section. Matters that were raised or that could have been raised in a hearing before the Secretary or in an appeal pursuant to subsection (d) of this section may not be raised as a defense to a civil action by the United States to collect a penalty or assessment assessed under this section.

(g) Notification of appropriate entities of finality of determination

Whenever the Secretary's determination to impose a penalty or assessment under subsection (a) of this section becomes final, he shall notify the appropriate State or local medical or professional organization, and the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in section 1395aa(a) and 1396a(a)(33) of this title) that such a penalty or assessment has become final and the reasons therefor.

(h) Definitions

For the purposes of this subsection:

(1) The term "State agency" means the agency established or designated to administer or supervise the administration of the State plan under subchapter XIX of this chapter or designated to administer the State's program under subchapter V of this chapter.

(2) The term "claim" means an application submitted by—

(A) a provider of services or other person, agency, or organization that furnishes an item or service under subchapter XVIII of this chapter, or

(B) a person, agency, or organization that furnishes an item or service for which medical assistance is provided under subchapter XIX of this chapter, or

(C) a person, agency, or organization that provides an item or service for which payment is made under subchapter V of this chapter or from an allotment to a State under such subchapter.

to the United States or a State agency, or agent thereof, for payment for health care services under subchapter XVIII or XIX of this chapter or for any item or service under subchapter V of this chapter.

(3) The term "item or service" includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.

(4) The term "agency of the United States" includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other claims processing agent for a health insurance or medical services program under subchapter XVIII or XIX of this chapter.

(Aug. 14, 1935, c, 531, Title XI, § 1128A, as added Aug. 13, 1981, Pub.L. 97-35, Title XXI, § 2105(a), 95 Stat. 789, and amended Sept. 3, 1982, Pub.L. 97-248, Title I, § 137(b)(26), 96 Stat. 380. As amended July 18, 1984, Pub.L. 98-369, Title III, §§ 2306(f)(1), 2354(a)(3), 98 Stat. 1073, 1100.)

APPENDIX F

42 U.S.C. § 1395x(r) (1983 & Supp. 1987).

(r) Physician

The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1301(a)(7) of this title), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsection (s) of this section but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them; and for the purposes of subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395k (a)(2)(F)(ii), and 1395n of this title but only if his performance of functions under subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii) and 1395n of this title is consistent with the policy of the institution or agency with respect to which he performs them and with the functions which he is legally authorized to perform, (4) a doctor of optometry, but only with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of subsections (s)(1) and (s)(2)(A) of this section and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation demonstrated by X-ray to exist) which he is legally authorized to perform by the State or jurisdiction in

which such treatment is provided. For the purposes of section 1395y(a)(4) of this title and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1395y(a)(4) of this title) are furnished.

(Aug. 14, 1935, c. 531, Title XVIII, § 1861, as added July 30, 1965, Pub.L. 89-97, Title I, § 102(a), 79 Stat. 313, and amended Nov. 2, 1966, Pub.L. 89-713, § 7, 80 Stat. 1111; Jan. 2, 1968, Pub.L. 90-248, Title I, §§ 127(a), 129(a), (b), (c)(9)(C), (10), (11), 132(a), 133, 134(a), 143(a), 144(a)-(d), 81 Stat. 846-850, 852, 857, 858; Jan. 12, 1971, Pub.L. 91-690, 84 Stat. 2074; Oct. 30, 1972, Pub.L. 92-603, Title II, §§ 211(b), (c)(2), 221(c)(4), 223(a)-(d), (f), 227(a), (c), (d)(1), (f), 234(a)-(f), 237(c), 244(c), 246(b), 248, 249(b), 251(a)(1), (b)(1), (c), 252(a) 256(b), 264(a), 265, 267, 273(a), 276(a), 278(a)(4)-(15), (b)(6), (10), (11), 283(a), 86 Stat. 1383, 1384, 1389, 1393, 1394, 1404-1407, 1412, 1413, 1416, 1423-1426, 1445-1447, 1449-1454, 1456; Dec. 31, 1975, Pub.L. 94-182, Title I, §§ 102, 106(a), 112(a)(1), 89 Stat. 1051, 1052, 1055; Oct. 25, 1977, Pub.L. 95-142, §§ 3(a)(2), 5(m), 19(b)(1), 21(a), 91 Stat. 1178, 1191, 1204, 1207; Dec. 13, 1977, Pub.L. 95-210, § 1(d), (g), (h), 91 Stat. 1485, 1487, 1488; Dec. 20, 1977, Pub.L. 95-216, Title V, § 501(a), 91 Stat. 1564; June 13, 1978, Pub.L. 95-292, § 4(d), 92 Stat. 315; Dec. 5, 1980, Pub.L. 96-499, Title IX, §§ 902(a)(1), 915(a), 930(k)-(n), (p), 931(c), (d), 933(c)-(e), 936(a), 937(a), 938(a), 948(a)(1), 949, 951(a), (b), 952, 94 Stat. 2612, 2623, 2632, 2633, 2635, 2639, 2640, 2643, 2645, 2646; Dec. 5, 1980, Pub.L. 96-499, Title IX, § 952(a), as amended Sept. 3, 1982, Pub.L. 97-248, Title I, § 127(1), 96 Stat. 366; Dec. 28, 1980, Pub.L. 96-611, § 1(a)(1), (b)(3), 94 Stat. 3566; Aug. 13, 1981, Pub.L. 97-35, Title XXI, §§ 2102(a), 2114, 2121(c), (d), 2141(a), 2142(a), 2143(a), 2144(a), 2193(c)(9), 95 Stat. 787, 796-799, 828; Sept. 3, 1982, Pub.L. 97-248, Title I, §§ 101(a)(2), (d), 102(a), 103(a), 105(a), 106(a), 107(a), 108(a)(2), 109(b)(1), (2), 114(b), 122(d), 128(a)(1), (d)(2), 148(b), 96 Stat. 335-339, 350, 359, 366, 367, 394; Sept. 3, 1982, Pub.L. 97-248, Title I, § 109(b)(2), as

amended Jan. 12, 1983, Pub.L. 97-448, Title III, § 309(a)(4), 96 Stat. 2408; Apr. 20, 1983, Pub.L. 98-21, Title VI, §§ 602(d), 607(b)(2), (d), 97 Stat. 163, 171, 172. As amended July 18, 1984, Pub.L. 98-369, Title III, §§ 2314(a), 2318(a), (b), 2319(a), 2321(e), 2322(a), 2323(a), 2324(a), 2335(b), 2340(a), 2341(a), (c), 2342(a), 2343(a), (b), 2354(b)(18)-(29), 98 Stat. 1079, 1081, 1082, 1085, 1086, 1090, 1093, 1094, 1101; Nov. 8, 1984, Pub.L. 98-617, § 3(a)(4), (b)(7), 98 Stat. 3295, 3296.) (As amended July 18, 1984, Pub.L. 98-369, Title III, §§ 2306(f)(1), 2354(a)(3), 98 Stat. 1073, 1100 Oct. 21, 1986, Pub.L. 99-509, Title IX, § 9317(a), (b), 100 Stat. 2008.)

APPENDIX G

42 U.S.C. §1395x(s) (1983 & Supp. 1985).

(s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients;

(C) diagnostic services which are —

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services;

(E) rural health clinic services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1) of this section, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(3) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary), and such services and supplies furnished as an incident to his services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) immunosuppressive drugs furnished, to an individual who receives an organ transplant for which payment is made under this subchapter, within 1 year after the date of the transplant procedure; and

(K)(i) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1)) of this section and which are performed by a physician assistant (as defined in subsection (aa)(3)) of this section under the supervision

of a physician (as so defined) in a hospital, skilled nursing facility, or intermediate care facility (as defined in section 1396d(c) of this title) or as an assistant at surgery and which the physician assistant is legally authorized to perform by the State in which the services are performed, and

(ii) such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished as an incident to a physician's professional service;

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition; and

(10)(A) pneumococcal vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations).

No diagnostic tests performed in any laboratory which is independent of a physician's office, a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such laboratory –

(11) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(12) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which –

(13) would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital; or

(14) is furnished under arrangements referred to in such paragraph (2)(C) unless furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are

met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

(Aug. 14, 1935, c. 531, Title XVIII, § 1861, as added July 30, 1965, Pub.L. 89-97, Title I, § 102(a), 79 Stat. 313, and amended Nov. 2, 1966, Pub.L. 89-713, § 7, 80 Stat. 1111; Jan. 2, 1968, Pub.L. 90-248, Title I, §§ 127(a), 129(a), (b), (c)(9)(C), (10), (11), 132(a), 133, 134(a), 143(a), 144(a)-(d), 81 Stat. 846-850, 852, 857, 858; Jan. 12, 1971, Pub.L. 91-690, 84 Stat. 2074; Oct. 30, 1972, Pub.L. 92-603, Title II, §§ 211(b), (c)(2), 221(c)(4), 223(a)-(d), (f), 227(a), (c), (d)(1), (f), 234(a)-(f), 237(c), 244(c), 246(b), 248, 249(b), 251(a)(1), (b)(1), (c), 252(a) 256(b), 264(a), 265, 267, 273(a), 276(a), 278(a)(4)-(15), (b)(6), (10), (11), 283(a), 86 Stat. 1383, 1384, 1389, 1393, 1394, 1404-1407, 1412, 1413, 1416, 1423-1426, 1445-1447, 1449-1454, 1456; Dec. 31, 1975, Pub.L. 94-182, Title I, §§ 102, 106(a), 112(a)(1), 89 Stat. 1051, 1052, 1055; Oct. 25, 1977, Pub.L. 95-142, §§ 3(a)(2), 5(m), 19(b)(1), 21(a), 91 Stat. 1178, 1191, 1204, 1207; Dec. 13, 1977, Pub.L. 95-210, § 1(d), (g), (h), 91 Stat. 1485, 1487, 1488; Dec. 20, 1977, Pub.L. 95-216, Title V, § 501(a), 91 Stat. 1564; June 13, 1978, Pub.L. 95-292, § 4(d), 92 Stat. 315; Dec. 5, 1980, Pub.L. 96-499, Title IX, §§ 902(a)(1), 915(a), 930(k)-(n), (p), 931(c), (d), 933(c)-(e), 936(a), 937(a), 938(a), 948(a)(1), 949, 951(a), (b), 952, 94 Stat. 2612, 2623, 2632, 2633, 2635, 2639, 2640, 2643, 2645, 2646; Dec. 5, 1980, Pub.L. 96-499, Title IX, § 952(a), as amended Sept. 3, 1982, Pub.L. 97-248, Title I, § 127(1), 96 Stat. 366; Dec. 28, 1980, Pub.L. 96-611, § 1(a)(1), (b)(3), 94 Stat. 3566; Aug. 13, 1981, Pub.L. 97-35, Title XXI, §§ 2102(a), 2114, 2121(c), (d), 2141(a), 2142(a), 2143(a), 2144(a), 2193(c)(9), 95 Stat. 787, 796-799, 828; Sept. 3, 1982, Pub.L. 97-248, Title I, §§ 101(a)(2), (d), 102(a), 103(a), 105(a), 106(a), 107(a), 108(a)(2), 109(b)(1), (2), 114(b), 122(d), 128(a)(1), (d)(2), 148(b), 96 Stat. 335-339, 350, 359, 366, 367, 394; Sept. 3, 1982, Pub.L. 97-248, Title I, § 109(b)(2), as amended Jan. 12, 1983, Pub.L. 97-448, Title III, § 309(a)(4), 96 Stat. 2408; Apr. 20, 1983, Pub.L. 98-21, Title VI, §§ 602(d), 607(b)(2), (d), 97 Stat. 163, 171, 172. As amended July 18, 1984, Pub.L. 98-369, Title III, §§ 2314(a), 2318(a), (b), 2319(a),

2321(e), 2322(a), 2323(a), 2324(a), 2335(b), 2340(a), 2341(a), (c), 2342(a), 2343(a), (b), 2354(b)(18)-(29), 98 Stat. 1079, 1081, 1082, 1085, 1086, 1090, 1093, 1094, 1101; Nov. 8, 1984, Pub.L. 98-617, § 3(a)(4), (b)(7), 98 Stat. 3295, 3296.)

APPENDIX H

42 U.S.C. § 1320a-7 (1983 & Supp. 1987).

§ 1320a-7. Exclusion of certain individuals from program

(a) Individuals convicted of Medicare of Medicaid related crimes; exclusion determination; notice to State and local agencies.

Whenever the Secretary determines that a physician or other individual has been convicted (on or after October 25, 1977, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to such individual's participation in the delivery of medical care or services under subchapter XVIII, XIX, or XX of this chapter, the Secretary—

(1) shall bar from participation in the program under subchapter XVIII of this chapter each such individual otherwise eligible to participate in such program;

(2)(A) shall promptly notify each appropriate State agency administering or supervising the administration of a State plan approved under subchapter XIX of this chapter of the fact and circumstances of such determination, and (except as provided in subparagraph (B)) require each such agency to bar such individual from participation in such plan for such period as he shall specify, which in the case of an individual specified in paragraph (1) shall be the period established pursuant to paragraph (1);

(B) may waive the requirement under subparagraph (A) to bar an individual from participation in a State plan under the subchapter XIX of this chapter, where he receives and approves a request for such a waiver with respect to that individual from the State agency administering or supervising the administration of such plan; and

(3) shall promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of such individual of the fact and circumstances of such determination, request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and request that such State or local agency or authority keep the Secretary and the Inspector General of the Department of Health and Human Services fully and currently informed with respect to any action taken in response to such request.

(b) Individuals with ownership or control of 5 percent or more; officers, directors, agents, or managing employees; exclusion determination; notice to State and local agencies

Whenever the Secretary determines, with respect to an entity, that a person who has a direct or indirect ownership or control interest of 5 percent or more in the entity, or who is an officer, director, agent , or manging employee (as defined in section 1320a-5(b) of this title) of such entity, is a person described in section 1320a-5(a) of this title, the Secretary—

(1) may bar from participation in the program under subchapter XVIII of this chapter, for such period as he may deem appropriate, each such entity otherwise eligible to participate in such program;

(2) shall promptly notify each appropriate State agency administering or supervising the administration of a State plan approved under subchapter XIX of this chapter of the fact and circumstances of the determination, and may require each such agency to bar the entity from participation under the State plan for such period as he specifies, which may not exceed the period established pursuant to paragraph (1); and

(3) shall promptly notify the appropriate State or local agency or authority having responsibility for the

licensing or certification of such entity of the fact and circumstances of such determination, request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and request that such State or local agency or authority keep the Services fully and currently informed with respect to any actions taken in response to such request.

(c) Individuals subject to civil sanction for Medicare or Medicaid misconduct; exclusion determination; notice to State and local agencies

Whenever the Secretary makes a final determination to impose a civil money penalty or assessment against a person (including an organization, agency, or other entity) under section 1320a-7a of this title relating to a claim under subchapter XVIII or XIX of this chapter, the Secretary–

(1) may bar the person from participation in the program under subchapter XVIII of this chapter, and

(2)(A) shall promptly notify each appropriate State agency adminstering or supervising the adminstration of a State plan approved under subchapter XIX of this chapter of the fact and circumstances or such determination, and (except as provided in subparagraph (B)) may require each such agency to bar the person from participation in the program established by such plan for such period as he shall specify, which in the case of an individual shall be the period established pursuant to paragraph (1), and

(B) may waive the requirement of subparagraph (A) to bar a person from participation in such program where he receives and approves a request for such waiver with respect to that person from the State agency referred to in that subparagraph.

(d) Period of exclusion

A determination made by the Secretary under this section shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of inpatient hospital services, post-hospital extended care services, and home health services furnished under subchapter XVIII of this chapter, such determination shall be effective in the manner provided in paragraphs (3) and (4) of section 1395cc(b) of this title with respect to terminations of agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(e) Notice, hearing, and judicial review

Any person or entity who is the subject of an adverse determination made by the Secretary under subsection (a), (b), or (c) or this section shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

(f) Physicians or other individuals convicted of criminal offenses

For purposes of subsection (a), a physician or other individual is considered to have been "convicted" of a criminal offense—

> (1) when a judgment of conviction has been entered against the physician or individual by a Federal, State or local court, regardless or whether there is an appeal pending or whether the judgment or conviction or other record relating to criminal conduct has been expunged;

(2) when there has been a finding of guilt against the physician or individual by a Federal, State or local court;

(3) when a plea of guilty or nolo contendere by the physician or individual has been accepted by a Federal, State, or local court; or

(4) when the physician or individual has entered into participation in a first offender or other program where judgment of conviction has been withheld.

(As amended July 18, 1984, Publ.L. 87-369, Title III, § 2333(a), (b), 98 Stat. 1089; Oct. 21, 1986, Pub.L. 99-509, Title IX, § 9317(c), 100 Stat. 2008.)

1984 Amendment. Subsec. (b). Pub.L. 98-369, § 2333(a)(2), added subsec. (b). Former subsec. (b) was redesignated (c).

Subsec. (c). Pub.L. 98-369, § 2333(a)(1), redesignated former subsec. (b) as (c). Former subsec. (c) was redesignated (d).

Subsec. (d). Publ.L. 98-369, § 2333(a)(1), redesignated former subsec. (c) as (d). Former subsec. (d) was redesignated (e).

Subsec. (e). Pub.L. 98-369, § 2333(a)(1), redesignated former subsec. (d) as (e).

Pub.L. 98-369, § 2333(b)(1), substituted "Any person or entity" for "Any person".

Pub.L. 98-369, § 2333(b)(2), substituted "(a), (b), or (c)" for "(a) or (b)".

Effective Date of 1986 Amendment. Section 9317(d)(3) of Pub.L. 99-509 provided that: "The provisions—

APPENDIX I

U.S. CONST. amends. V, XIV

AMENDMENT V—CAPITAL CRIMES; DOUBLE JEOPARDY; SELF-INCRIMINATION; DUE PROCESS; JUST COMPENSATION FOR PROPERTY

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

AMENDMENT XIV.—CITIZENSHIP; PRIVILEGES AND IMMUNITIES; DUE PROCESS; EQUAL PROTECTION; APPORTIONMENT OF REPRESENTATION; DISQUALIFICATION OF OFFICERS; PUBLIC DEBT: ENFORCEMENT

Section 1. All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; or deny to any person within its jursidiction the equal protection of the laws.